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REVIEW OF THE PUBLIC HEALTH SERVICE'S RESPONSE TO AIDS

A TECHNICAL MEMORANDUM

FEBRUARY 1985

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Foreword

This memorandum was prepared in response to a request by the Subcommittee on Health and the Environment, House Committee on Energy and Commerce, and the Subcommittee on Intergovernmental Relations and Human Resources, House Committee on Government Operations. The Office of Technology Assessment (OTA) had been conducting an assessment of *Blood Policy and Technology* (published in January 1985) for the House Committee on Energy and Commerce when transfusion-related cases of acquired immunodeficiency syndrome (AIDS) began to appear. We were subsequently asked to review the recent and proposed activities of the Public Health Service (PHS) in response to AIDS, and to evaluate the planning, resources and staffing of PHS's efforts to control AIDS.

OTA was asked to examine both technical aspects of research and related issues of public health policy, in particular:

- the adequacy of PHS's confirmation of the causal relationship between the newly discovered retrovirus HTLV-III and AIDS and the adequacy of research to identify other possible agents involved;
- the adequacy and timeliness of PHS's redirection of general AIDS research toward HTLV-III work, including research on blood, on treatment protocols, on animal models, and on epidemiological work;
- the adequacy and scope of efforts to develop vaccines against the disease;
- the adequacy and timeliness of the distribution of new knowledge and information among researchers and regulators; and
- the adequacy of PHS resources to support needed activities that would yield the best chances for immediate results in the prevention and treatment of AIDS.

These questions and related issues of science and public policy are addressed in this memorandum.

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Contents

Chapter *Page*
1. SUMMARY ... 3
   The Biology of AIDS ... 4
   Federal Support of AIDS Research ... 6
   Related Issues ... 8
2. SPECIFIC FINDINGS ... 13
   Is There an Adequate Correlation Between HTLV-III and AIDS? ... 13
   How Has the Public Health Service Redirected Its AIDS Research Toward HTLV-III Work? ... 16
      Blood Studies ... 17
      Epidemiologic Studies ... 17
      Treatment Protocols ... 20
      Animal Models ... 21
   What About Efforts To Develop an AIDS Vaccine? ... 22
      Subunit Vaccine From Cultured Virus ... 24
      Recombinant DNA Vaccine ... 24
      Infectious Recombinant Vaccine ... 24
      Anti-Idiotype Vaccine ... 25
      Prospects for a Successful Vaccine ... 25
   Has the Distribution of New Information Among Researchers and Regulators Been Adequate and Timely? ... 26
      NCI and CDC Sharing of HTLV-III Culture Samples ... 28
      DHHS Announcement of the Discovery of HTLV-III ... 28
      Funding of Extramural Research ... 29
      Federal Policy on Commercial Development ... 30
      Conclusion ... 30
   How Adequate Are PHS's Resources Devoted to AIDS Prevention and Treatment? ... 31
      Specific Funding for AIDS Activities ... 32
      Funding for the PHS Agencies as a Whole ... 36
      How AIDs and Other Activities Have Been and Will Probably Be Affected by Funding Patterns ... 39
      Measures To Increase the Number of Extramural Research Projects ... 41
      Resources for Research on Cofactors and Treatment and for Public Education ... 42
      PHS View and OTA Conclusions ... 44
   Related Issues ... 47
      Confidentiality and Informed Consent ... 47
      Prevention Through Education ... 49
      Financing of Clinical and Supportive Services ... 51
   Conclusions ... 52

Appendixes *Page*
A. Acknowledgments and Health Program Advisory Committee ... 57
B. PHS Organization Chart ... 63
C. OASH Summary of Individual PHS Agencies' Obligations for Specific AIDS Activities, Fiscal Years 1984 and 1985 ... 64

Contents—Continued

Appendixes *Page*

D. Individual PHS Agencies' and OASH Office of Public Affairs' Anticipated AIDS-Related Grants and Activities, Fiscal Year 1985 and NIH AIDS Projects Funded in Fiscal Years 1983 and 1984 77
E. A Partial List of Organizations Involved in AIDS Lobbying, Public Education, Prevention, or Social Services 141
F. Glossary of Acronyms and Terms 145

References 151

List of Tables

Table No. *Page*

1. History of AIDS Funding, Fiscal Years 1982 to 1985 32
2. PHS Agencies' Estimated Obligations for AIDS Activities in Fiscal Year 1984 . . . 34
3. Supplemental Funds for PHS Agencies' AIDS Activities in Fiscal Year 1984: Agencies' Indications Compared to Congressional Appropriations 34
4. Amounts Identified for PHS Agencies' AIDS Activities for Fiscal Year 1985: President's Budget Request Compared to Congressional Appropriations or Estimated Actual Obligations 35
5. Centers for Disease Control: Initial U.S. Budget Request Compared to Estimated Budget Authority for Previous Year, Fiscal Years 1983 to 1985 36
6. Centers for Disease Control: Overall Agency Budgets and AIDS Budgets, Fiscal Years 1979 to 1985 36
7. Food and Drug Administration: Initial U.S. Budget Request Compared to Estimated Budget Authority for Previous Year, Fiscal Years 1983 to 1985 37
8. Food and Drug Administration: Overall Agency Budgets and AIDS Budgets, Fiscal Years 1979 to 1985 37
9. National Institutes of Health: Initial U.S. Budget Request Compared to Estimated Budget Authority for Previous Year, Fiscal Years 1983 to 1985 37
10. Alcohol, Drug Abuse, and Mental Health Administration: Initial U.S. Budget Request Compared to Estimated Budget Authority for Previous Year, Fiscal Years 1983 to 1985 38
11. Alcohol, Drug Abuse, and Mental Health Administration: Overall Agency Budgets and AIDS Budgets, Fiscal Years 1982 to 1985 38
12. Health Resources and Services Administration: Initial U.S. Budget Request Compared to Estimated Budget Authority for Previous Year, Fiscal Years 1983 to 1985 38
13. National Institute of Allergy and Infectious Diseases: Redistribution Needed To Fund Fiscal Year 1985 AIDS Activities 40
14. National Cancer Institute: Estimated Redistribution Needed To Fund Fiscal Year 1985 AIDS Activities 41
15. National Institutes of Health: Award Rates and Paylines for All Extramural Research Compared to AIDS Extramural Research, Fiscal Year 1983 42
16. Changes in Funding for PHS AIDS Activities Anticipated After Discovery of AIDS Etiologic Agent 43
17. Funding for PHS AIDS Activities by Type of Activity, Fiscal Years 1984 and 1985 43
18. Funding for PHS AIDS Activities by Type of Activity and Agency, Fiscal Years 1984 and 1985 45

Chapter 1
Summary

Chapter 1

Summary

The basic cause of acquired immunodeficiency syndrome (AIDS) is almost certainly a newly discovered virus, human T-cell lymphotropic virus, type III, or "HTLV-III." Researchers who have isolated viruses similar to HTLV-III have given their isolates other descriptive names, such as "lymphadenopathy-associated virus" (LAV) or "AIDS-related virus" (ARV), but these isolates and HTLV-III are essentially the same.

The AIDS virus preferentially infects and destroys certain white blood cells called "T lymphocytes" that are essential for the functioning of the body's immune system. When the immune system is severely depressed or destroyed by HTLV-III, other infectious agents such as bacteria or other types of viruses that usually do not cause disease in persons with normal immune functions may have the opportunity to cause disease ("opportunistic infections") because of the body's weakened defenses. Different types of cancer may also occur with severe depression of the immune system by HTLV-III infection. The cause of these cancers is not certain, but it may be a combination of depressed immune functions and infection with other viruses, or perhaps involve infection by the HTLV-III virus itself.

As more has been learned about the ability of HTLV-III to cause disease, it has become apparent that a broad spectrum of clinical responses can occur. Some people have been infected and shown few or no immunologic abnormalities and no evidence of illness, others have had severe effects on their immune systems and developed fulminant and fatal AIDS, while others have manifested responses between these two extremes. Associated risk factors are under examination and will help in understanding why some people exposed to HTLV-III remain well while others progress to different stages of clinical illness. **Since AIDS is a newly discovered disease and the time between exposure and the onset of clinical disease can take several years, it is too soon to tell what percentage of persons exposed to the virus will develop AIDS. It is also too soon to tell whether persons exhibiting milder manifestations of disease (e.g., fever, some depression of immune functions, enlarged lymph nodes) will eventually develop AIDS, continue to exhibit signs and symptoms of mild disease, or get well.**

Prior to the discovery of the etiologic (causative) agent for AIDS, efforts to devise preventive and treatment strategies had to depend on empirical observations of AIDS's epidemiology and effects on the body. **The discovery of HTLV-III now provides a theoretical foundation which greatly expands the range of possible strategies to prevent, diagnose, and treat AIDS.** It is important to recognize, however, that the discovery of HTLV-III only begins the next phase of efforts to control AIDS. Thus, it remains to be seen whether the new knowledge that is gained can be used to develop effective drugs and vaccines within a few years. Meanwhile, the number of persons infected with the virus and the number of AIDS cases continue to grow rapidly.

The activities of the U.S. Public Health Service (PHS) have laid down most of the foundation for addressing the AIDS epidemic. PHS grantees "discovered" AIDS as a syndrome; PHS has conducted surveillance of AIDS; and PHS investigators and others have made significant scientific advances, including the discovery of the probable etiologic agent for AIDS. PHS is currently coordinating development of a blood test for HTLV-III antibodies; and research on AIDS treatment, vaccine development, and the many remaining questions about the natural history of the disease is progressing. Furthermore, PHS investigators at present are extensively involved in collaborations with non-Federal researchers, both nationally and internationally. **It has not always been clear, however, that the amount of support for AIDS activ-**

ities has been equivalent to the effort that individual researchers and PHS agencies believe is necessary. Furthermore, there are issues that extend beyond the biological nature of AIDS which warrant more attention from the Federal Government—prevention of AIDS through education, confidentiality and informed consent for research and blood donation, and support for the clinical and financial needs of AIDS patients.

THE BIOLOGY OF AIDS

When the code contained in the DNA (deoxyribonucleic acid) of a cell's genes is to be "translated" to produce a product such as a protein, an RNA (ribonucleic acid) copy of the relevant piece of DNA is "transcribed," and the RNA copy then travels to the cell's production site, where it serves as a template for protein production. Collectively, this process is termed "gene expression."

HTLV-III belongs to a group of viruses called "retroviruses," which are so named because they can reverse the process of gene expression when they infect cells. Retroviruses contain RNA, not DNA, but reproduce by incorporation into the DNA of the cells they infect. In order to be incorporated into a host cell's DNA, the retroviral RNA must be transcribed into its DNA counterpart. An enzyme that the retrovirus produces, called "reverse transcriptase," accomplishes this process. When the retrovirus is ready to reproduce, it initiates the normal process of gene expression whereby DNA is transcribed into RNA but at a greatly accelerated rate, spewing out copies of the retrovirus in its original RNA form.

HTLV-III attacks what is commonly referred to as the "helper/inducer" subset of T lymphocytes, or, more accurately, the "T4" subset. T lymphocytes are classified into various subsets. One method of classification distinguishes between T cells that function to "help" and T cells that function to "suppress" immune functions as the immune system is activated and then is fine-tuned when the body is invaded by foreign materials. T lymphocytes can also be classified by the different molecules on their cell surfaces through the use of monoclonal antibodies that recognize each type of surface molecule as a separate and unique antigen. One such classification system separates T lymphocytes into those that have "T4" and those that have "T8" molecules on their surface (named after the monoclonal antibodies used to distinguish between these two types of surface molecules or antigens). Functional and surface molecule methods of classification result in overlapping categories. Commonly, however, even though both the "T4" and "T8" subsets contain cells that help and cells that suppress immune responses, the "T4" subset is referred to as the "helper/inducer" subset of T lymphocytes, and the "T8" subset, as the "suppressor" subset.

The primary defect in AIDS is an acquired, persistent, quantitative, and functional depression of T4 lymphocytes. The T4 cell membrane molecule that defines the T4 subset of T lymphocytes is now known to be an essential component of the cell-surface receptor for HTLV-III; i.e., interaction between the HTLV-III virus and the T4 molecule is apparently the way in which the virus gains entry into the cell.

The T4 molecule can be found not only on T4 lymphocytes but also on some other types of white blood cells that perform a scavenging or phagocytic function by engulfing foreign material and consuming debris and foreign bodies. This observation raises the question of whether these other white blood cells may also become infected with HTLV-III. Furthermore, brain cells and T lymphocytes are known to share some common cell surface molecules, and recent evidence has shown that the brain of an AIDS patient can be infected and the virus reproduced there. Infection of the brain would further complicate future treatment prospects because of the general difficulty in getting drugs into the central nervous system.

The availability of various tests for HTLV-III should result in a more precise delineation of the natural history of AIDS. Studies of different populations at risk, their variations in associated risk factors and in clinical responses upon exposure to HTLV-III, are of immediate relevance to our understanding of how the disease spreads, preventive strategies, and the possibility of early treatment. For example, the human immune system will produce antibodies to whatever antigens are encountered, so the mere presence of antibodies to HTLV-III does not necessarily mean that the types of antibodies that will *neutralize* the virus have been produced. By studying persons who are at high risk for AIDS but who have not developed the disease, scientists may discover which of the several antibodies that are produced in response to infection with HTLV-III might neutralize the virus.

Production of antibodies upon exposure to HTLV-III is also the basis for a blood test that will be used initially for screening blood donations and plasma collections. It is now known, however, that some persons can be infected with the virus but have no current symptoms of disease and not produce antibodies. The blood test for antibodies to HTLV-III, therefore, will not replace screening procedures designed to exclude potential blood donors in groups at high risk for AIDS. Because of current technical capabilities, the first-generation blood test relies on detection of antibodies to HTLV-III instead of detection of the virus itself (or its parts). Large quantities of HTLV-III can now be grown and used as the antigen to detect antibodies in tested blood. Methods to mass produce antibodies to detect the presence of viral antigens in tested blood, however, have yet to be developed.

Use of the blood test raises difficult issues pertaining to informed consent and confidentiality, because the meaning of a positive test, other than evidence of exposure to HTLV-III, is uncertain. Does a positive result mean that a person who has antibodies to the virus is also infected with it? This question can be answered on a case-by-case basis by a few researchers who have the capability to test for the presence of the virus, but the capacity to perform such tests routinely has yet to be developed. What are the chances that an antibody-positive person will develop AIDS? The answer to this question will only come after long-term monitoring of persons who are HTLV-III antibody-positive.

The discovery of HTLV-III makes possible the tentative confirmation that newer methods of preparing antihemophilic factors from plasma can inactivate the virus. Some plasma protein products, such as albumin, are already heated to temperatures that inactivate most viruses without causing these products to lose their activity. However, the coagulation proteins are not as resilient in preserving their activity when heated. Improvements in heat treatment using buffers to protect the proteins during heating, however, have recently been shown to inactivate some viruses, and with the availability of HTLV-III for testing, these new methods and further improvements on them have been shown to inactivate HTLV-III. (The cellular elements of blood that are used in transfusions—red blood cells and platelets—and fresh plasma, would be destroyed by the temperatures necessary to inactivate HTLV-III.)

The discovery of HTLV-III also makes possible the development of more specific therapeutic approaches to AIDS. Cultures of T lymphocytes mixed with HTLV-III can be used to test drugs that might inhibit infection by HTLV-III. At least three drugs, suramin, ribavirin, and HPA-23, have been shown to inhibit infection by blocking the action of the reverse transcriptase enzyme and are now being tested in limited clinical trials. More importantly, **the life cycle of the virus is now under study, and theories based on the understanding gained will lead to multiple therapeutic approaches.** Thus, for example, the experiments leading to the discovery that the T4 molecule on T4 lymphocytes was an essential component of the cell-surface receptor for HTLV-III raise the possibility of using monoclonal antibodies against the T4 molecule to block the virus's entry into the cell.

The development of a vaccine against HTLV-III, using novel as well as established methods, is now under way. The many unknowns associated with HTLV-III make it prudent to develop a vaccine that does not contain the virus's genetic material, so current efforts are focused on finding and using the part ("subunit") of the virus that would elicit the proper antibody to neutralize the virus. Current efforts to develop a "subunit" vaccine include breaking down the virus and testing its various parts; taking the gene that corresponds to the particular part of the virus under study and inserting it through recombinant DNA techniques into bacteria, yeast, or mammalian cells so that the subunit can be produced in quantity; inserting the corresponding gene into other, benign viruses (e.g., into vaccinia virus, used to immunize against smallpox) with the intention of using those viruses as the vaccine; and developing copies of the relevant viral subunit through novel manipulations of antigen-antibody interactions.

Despite these rapid developments in vaccine research, serious obstacles remain. The first is that most of the newer techniques are largely experimental, the first of the vaccines from the most understood recombinant DNA techniques (i.e., a vaccine for hepatitis B) having just become available. Second, there is evidence that the genes which code for the parts of the virus that would be most likely to make an effective vaccine (i.e., the surface membrane or "envelope" of the virus) change frequently, although not drastically. If these genetic mutations are significant enough that their corresponding protein molecules change their antigenic characteristics, it will be difficult to develop an effective vaccine.

In contrast to these promising developments in understanding the biology of AIDS are the ever growing number of AIDS patients and the rapidly enlarging pool of persons who have been exposed to HTLV-III and who may be carriers of the virus. The total number of AIDS cases reported to the Centers for Disease Control (CDC) by the end of 1984 was approximately 7,000, and the number of reported cases has been doubling every year—fewer than 900 cases prior to December 1982, more than 2,000 cases in 1983, and almost 4,000 cases in 1984. Seventy-three percent of patients diagnosed before January 1983 have died. **Forty thousand new cases are expected to be reported in the United States in the next 2 years.** Furthermore, surveys of high-risk groups (gay men, intravenous drug abusers, hemophiliacs) for the presence of antibodies to HTLV-III in their blood have shown marked increases in positive rates since about 1980, with current positive rates between 65 and 90 percent in some of the tested populations.

AIDS is not only a problem in the United States. There are at least 500 cases in the rest of the Americas, 600 in Europe, and several thousand in central Africa. **In some parts of central Africa, where infection with the HTLV-III virus appears to predate infections in the United States, heterosexual transmission appears to be common and may be the predominant mode of transmission. Heterosexual transmission has occurred in the United States, but is still relatively uncommon and has been primarily from males to their female partners, particularly in the intravenous drug abuser group.** A significant portion of U.S. female intravenous drug abusers practice prostitution, and the possibility of increased female-to-male transmission and risks associated through contacts with prostitutes are under study.

Thus, while significant advances in understanding the biology of the AIDS virus are occurring and may lead to effective therapeutic drugs and a vaccine, the number of persons exposed to the virus and probably carrying it and the number of AIDS cases continue to increase at an accelerated pace.

FEDERAL SUPPORT OF AIDS RESEARCH

The U.S. Department of Health and Human Services (DHHS) has designated AIDS as its number one health priority, and much of what we know about the biology of AIDS is a result of federally sponsored activities. However, the Department's position has been that funds for AIDS activities should be transferred from other PHS activities, and increases in funding specifically for AIDS activities have come at the initiative of Congress, not from DHHS. Personnel ceilings have been a special problem.

Although AIDS funding has been substantial, particularly in fiscal years 1984 and 1985, the history of specific funding for AIDS has been marked by tension among the individual PHS agencies, DHHS, and Congress. **Through the Assistant Secretary for Health, individual PHS agencies have consistently asked DHHS to request particular sums from Congress; the Department has submitted requests for amounts smaller than those suggested by the agencies; and Congress typically has appropriated amounts greater than those requested by the Department.** Except when prodded by Congress, the Department has maintained that PHS agencies should be able to conduct AIDS research without extra funds. However, threatened cuts in overall funding and personnel levels have restricted the ability of affected agencies to redirect resources. **Of greater impact than holding general funding of PHS agencies about even or decreasing it have been budget requests for decreases in personnel ceilings. At critical times, several of the PHS agencies have actually experienced decreases in personnel.**

PHS agencies have been unable to plan their activities adequately because they have not known how much funding and staff will be available to them. Furthermore, the uncertain distribution of resources has intensified competition among agencies now that an etiologic agent for AIDS has been discovered and there are many directions for research to take concurrently (e.g., treatment, vaccine development, cofactor research, natural history studies) and several areas in which agencies have overlapping expertise.

In addition to the question of whether or not sufficient resources are being allocated to PHS agencies' AIDS activities by DHHS and Congress, there remains the question of whether resources are being allocated adequately to the various AIDS activities. In particular, doubts have been raised about the adequacy of resources devoted to the search for factors affecting transmissibility, the provision of treatment, and prevention through public education.

In general, the search for factors affecting the development of AIDS has always accounted for a large proportion of the AIDS budget. For both fiscal years 1984 and 1985, greater amounts were budgeted for cofactor research and epidemiologic studies after the discovery of HTLV-III than before its discovery. PHS estimates that 12.6 percent of the resources allocated to AIDS in fiscal year 1984 were obligated to cofactor research and 31.9 percent to epidemiologic studies. In fiscal year 1985, a relatively greater proportion (14.9 percent) of total AIDS resources will be obligated to cofactor research, but substantially less as a percentage of the total (26 percent) will be obligated to epidemiologic studies than in fiscal year 1984. In total dollars, however, almost $5 million more will be obligated to epidemiologic studies in fiscal year 1985 than in fiscal year 1984, and $6 million more to cofactor research.

About 2.1 percent of the AIDS budget for fiscal year 1985, or nearly $2 million, is being spent for research on psychosocial factors related to AIDS. As defined by PHS, this category includes research into the psychosocial consequences of AIDS as well as research into the contribution of these factors to the development of AIDS. Psychosocial risk factors include life stress, exhaustion, health habits, depression, anxiety, coping mechanisms, a sense of helplessness, and the loss of social support.

Approximately 14.8 percent of the AIDS budget for fiscal year 1985 is devoted to research on treatment (8.8 percent for the etiologic agent, and 6 percent for opportunistic infections). Except for treatment given to AIDS patients at the National Institutes of Health's Clinical Center, which is a research hospital, no funds have been allocated to the treatment of patients per se.

In the past, relatively few funds were allocated to public education. Between 1984 and 1985, however, the amount allocated to such activities more than doubled, from $1.4 million to $3.8 million, most of it for CDC. The AIDS budget in PHS's Office of Public Affairs, which has maintained the AIDS hotline, the *Facts About AIDS* newsletter, and developed booklets and a videotape about AIDS, is scheduled to decrease from $200,000 in fiscal year 1984 to $120,000 in fiscal year 1985.

Whether information about AIDS has been generated and disseminated on an adequate and timely basis has also been a cause of recurrent concern. The involvement of multiple organizations in similar research activities but addressed at different aspects of a common problem is arguably the best scenario for research. However, it means that researchers are constantly striving to keep abreast of the work of others.

In addressing AIDS, sharing of information has taken place through the informal networks that exist among PHS agencies and among their researchers and has been augmented by coordinating committees, external advisory committees, conferences, and cooperative agreements on funding extramural research and conducting intramural research. Most of these sharing and coordinating activities would have taken place regardless of any directive from PHS central management. In some instances, however, PHS (or departmental level) guidance might have led to better coordination—e.g., PHS might have directed the National Cancer Institute to share virus cultures with CDC. Finally, the announcement by the Secretary of DHHS of the discovery of the etiologic agent for AIDS appears to have been too optimistic regarding the use of a blood test to screen for exposure to HTLV-III and did not take into account the social implications and ethical dilemmas that would have to be addressed when persons who might be carriers of the HTLV-III virus were identified through a blood test.

Two factors which may have impeded the generation and dissemination of information are matters of more generalizable policy concerns. First, in the context of a public health emergency such as AIDS, the Federal grants application and approval process for extramural research works too slowly. Second, although private industry is involved in similar research and development activities, Federal regulations concerning commercial development of drugs, biologics, and devices mean that much of the information generated is not available to other researchers. A systematic examination of these more generalizable concerns is needed.

Thus, OTA finds that while the Federal Government has designated AIDS our country's number one health priority, increases in funding specifically for AIDS activities have come at the initiative of Congress, and PHS agencies have had difficulties in planning their AIDS-related activities because of uncertainties over budget and personnel allocations. Furthermore, in some instances, coordination between PHS researchers and between DHHS policymakers and PHS researchers could have been better managed. Two general questions that need further examination are: 1) how Federal research funding can be accelerated in public health emergencies without compromising the quality of research to be supported, and 2) how access to commercially sponsored research might be improved without infringing on the property rights of commercial enterprises.

RELATED ISSUES

It will be some time before the new knowledge that has been gained about AIDS can be expected to be translated into effective preventive and therapeutic interventions. In the interim, and probably even if biological remedies for the disease become available, prevention of AIDS through education about ways of minimizing exposure to HTLV-III has the greatest potential of limiting the spread of this disease. So far, efforts to prevent AIDS through education have received minimal funding, especially efforts targeted at the groups at highest risk.

The issues of confidentiality and informed consent, first arising in the context of treatment of AIDS patients and participation in AIDS-related research projects, will soon be a major concern as tests for evidence of exposure to or infection by HTLV-III become generally available. Confidentiality safeguards can be improved without sacrificing the surveillance needs of public health officials or data sharing among researchers. Informed consent will be an especially difficult issue, because the first tests to be applied will detect exposure to HTLV-III through the presence or absence of antibodies. However, persons who test positive will not be able to know whether they are actually carriers of HTLV-III, will develop AIDS, or will remain well. **These developments portend even more widespread and serious implications for our country's public health and social policies.** Decisions will have to be made soon that attempt to balance the public health concerns surrounding the transmissibility of AIDS from persons who have antibodies against HTLV-III versus the stigma that may attach to these persons, which could lead to their exclusion from some occupations and perhaps to even greater isolation from the rest of society.

Finally, providing and assisting in paying for clinical and supportive services is already a significant problem in those areas of the country with relatively large numbers of AIDS patients. This situation will worsen as the number of AIDS patients increases and if new treatments prolong life but do not restore health. To date, the Federal response has focused on the biomedical aspects of AIDS, so the primary responsibility for AIDS-related activities has rested with PHS. The potential contribution of PHS agencies to the provision and financing of service needs is severely limited by the nature of their responsibilities. Thus, if the Federal Government is to respond to the service needs of AIDS patients, Federal activities will have to expand beyond those attributable to PHS and at a minimum involve other organizational units within DHHS, such as the Health Care Financing Administration.

Chapter 2

Specific Findings

Chapter 2

Specific Findings

IS THERE AN ADEQUATE CORRELATION BETWEEN HTLV-III AND AIDS?

There is strong and increasing evidence that the newly discovered retrovirus HTLV-III (human T-cell lymphotropic virus, type III) (57,122,130,132) is the basic cause of acquired immunodeficiency syndrome (AIDS). HTLV-III is similar to, but nevertheless distinct from, two previously identified human T-cell lymphotropic retroviruses, HTLV-I and HTLV-II. HTLV-I and possibly HTLV-II cause T-cell leukemias (proliferation), whereas HTLV-III causes T-lymphocyte death (suppression). (Lymphocytes and other blood cells originate in the bone marrow. T cells or lymphocytes are white blood cells that mature in the thymus gland and mediate cellular immune reactions by helping ("helper T cells") or suppressing ("suppressor T cells") immune responses. B lymphocytes or cells are white blood cells that mediate humoral (e.g., antibody production) immune reactions and proliferate under stimulation from factors released by T lymphocytes.)

The genetic material of "retroviruses" consists of ribonucleic acid (RNA), not deoxyribonucleic (DNA), but when retroviruses infect cells, they are incorporated in the DNA of infected cells in a DNA form known as the "provirus." When retroviruses invade cells, they can reverse the process of "gene expression" by which information contained in the cells' genes is transcribed from DNA to RNA and then translated to direct the synthesis of proteins. Through the production of the enzyme "reverse transcriptase," retroviruses produce a DNA analog of their own RNA. The resulting DNA is then incorporated in the genetic structure of the invaded cell as the "provirus." Subsequently, the genetic information in the incorporated DNA is "expressed" in the usual way to produce new retroviruses.

HTLV-III is essentially the same virus as other retroviruses that have been associated with AIDS—LAV or "lymphadenopathy-associated virus" (7), IDAV or "immune-deficiency-associated virus" (107) and ARV or "AIDS-related virus" (89). The mild confusion that has resulted from the giving of different names by researchers to what appears to be the same virus is primarily the result of scientific caution.

When a possible agent for a new disease is reported, early published accounts provide the details of the investigations, and the investigator assigns a name to the agent. As Broder and Gallo (23) have observed with respect to the viruses associated with AIDS: "In theory, each isolate might have been a different, newly discovered human retrovirus presenting as an opportunistic infection, with no bearing on the pathogenesis of AIDS."

French investigators named their first isolate "lymphadenopathy-associated virus" (LAV) because it was isolated from a patient with lymphadenopathy syndrome, and they named a subsequent isolate "immune-deficiency-associated virus" (IDAV) because it was isolated from a patient with AIDS. In a later report on two other patients, these investigators found isolates (or antibodies to them) that were similar to both LAV and IDAV (172). Gallo and his coworkers at the National Cancer Institute (NCI) named their isolates "HTLV-III" because they were closely related to, but distinct from, two other recently discovered human T-cell lymphotropic retroviruses that Gallo and his associates had been extensively studying. Gallo and his coworkers have now accumulated over 90 isolates of HTLV-III from around the world (23). Finally, when Levy and his associates published findings on their isolate, they chose yet another name, "AIDS-related virus" (ARV), even though they found that it cross-reacted with antiserum to the LAV isolated in France (89).

Investigators in a study that examined antibody reactivity to both HTLV-III and LAV have found the results to be identical (32). Gallo and his coworkers have also reported that they have found these variously named retroviruses "immunologically and morphologically indistinguishble from HTLV-III" (66). All of these isolates ave now been cloned (1,66,91), and direct comparisons of the nucleotide sequences of the genomes of the various isolates are being conducted 56). In this memorandum, therefore, the various solates will be collectively referred to as "HTLV-II."

HTLV-III attacks what is commonly referred o as the helper/inducer subset of T lymphocytes, he cells which are attacked (depleted) in AIDS. T lymphocytes are classified into various subsets, wo of which are T4 and T8 (named after the ionoclonal antibodies used to distinguish the an-genically distinct subsets from each other). Al-hough T4 cells have commonly been identified vith helper/inducer functions and T8 cells with uppressor/cytotoxic functions, both subsets con-ain cells that help and cells that suppress immune esponses (133).

The primary defect in AIDS is an acquired, per-istent, quantitative and functional depression in he T4 lymphocytes (45,133). Patients with lymph-denopathy syndrome have been found to have a elective depression in a subset of T4 cells, but o have normal numbers of cells in the subset of T4 cells that are the major helper subset for B cell esponses (115). HTLV-III has a selective tropism or T4 lymphocytes (80), and the immune defects bserved in AIDS are completely compatible with he cellular defects associated with HTLV-III in-ections (46).

Furthermore, the T4 cell membrane molecule hat defines the T4 subset of T lymphocytes is now nown to be an essential component of the cell-urface receptor for HTLV-III; i.e., interaction be-ween HTLV-III and the T4 cell membrane mole-ule is apparently the way in which HTLV-III ains entry into the cell (39,81). These findings trongly suggest that HTLV-III tropism depends n the interaction of HTLV-III with the T4 molecule.

Most infectious retroviruses (including HTLV-I nd HTLV-II) use receptors common to many cell ypes. HTLV-III, in contrast, appears to use the urface receptor molecule specific to the cells (T4 ymphocytes) most affected by HTLV-III infec-ion (39). The T4 receptor molecule can be found n some types of white blood cells other than T4 lymphocytes. Such cells include macrophages and monocytes, which perform a scavenging or phagocytic function by engulfing foreign material and consuming debris and foreign bodies. These other white blood cells may also become infected with the virus (65a), adding to the compromised immune function in AIDS patients.

Brain cells and T lymphocytes are known to share some common cell surface molecules, and on the basis of this knowledge, some researchers decided to examine whether HTLV-III can infect brain cells. Their findings suggest that some of the neurological abnormalities found in AIDS, instead of being caused by "opportunistic" infectious agents or tumors, are directly caused by HTLV-III infection (135). Although the investigators showed that infection was not due to infiltration of the brain by HTLV-III-infected lymphocytes, the brain cell type or types directly infected by HTLV-III—neurons, glial cells (cells which provide the supporting tissue of the brain), or macrophages (scavenger cells)—have yet to be determined. The finding that HTLV-III can directly infect brain cells and replicate in the central nervous system means that future drug treatment for HTLV-III infections will be made more difficult because many drugs will not enter the central nervous system if given orally or by intramuscular or intravenous injections.

HTLV-III also has unusual properties that make it especially virulent. When a retrovirus infects cells, its RNA is transcribed into DNA, which is then integrated into the genome of the infected cells. Normally, this viral DNA is present in the cytoplasm of the infected cells only for a short period of time before it is integrated into the cells' genome. With HTLV-III, however, a substantial amount of unintegrated viral DNA persists in the cytoplasm. Although a persistence of unintegrated viral DNA is unusual for retroviruses, when observed with certain animal retroviruses, it has been correlated with pathological effects on the infected cells (134).

Furthermore, when HTLV-III that is integrated in its "provirus" form in the genome of infected cells begins to reproduce, special viral genes direct the rate of reproduction. These special genes have been shown to increase the rate of gene expression of infected cells by 100 to 1,000 times the rate of expression of uninfected cells. Thus, HTLV-III is a very efficient reproducer, there being a high level of virus production in HTLV-III infections which is unusual in HTLV-I and HTLV-II infections (140).

What is now known about the cellular mechanisms associated with infection with HTLV-III is compatible with certain characteristics in most of the population groups that have been identified as being at high risk for AIDS. For example, T cells that have been activated by antigenic stimuli, but not resting T cells, are especially prone to infection by HTLV-III (102). Homosexual and bisexual males who have frequent sexual intercourse with multiple partners are exposed to a variety of infectious agents that usually do not cause disease but do stimulate the immune system. Injections in intravenous drug abusers lead to stimulation of the immune system because of the injected drugs themselves and contamination with infectious agents. Injections with Factor VIII concentrates in hemophiliacs also lead to stimulation of the immune system.

There is also a correlation between exposure to HTLV-III and the development of AIDS. The HTLV-III virus has been cultured from patients with AIDS, AIDS-related complex, and persons at high risk for developing AIDS; HTLV-III has been observed by electron microscopy in the T cells of these groups; and antibodies to HTLV-III as well as HTLV-III antigens and the genes for HTLV-III have been isolated in these same groups. HTLV-III can now be recovered from over 90 percent of patients with AIDS-related complex (23); and, with the development of increasingly more sensitive tests, antibodies to HTLV-III can be detected in nearly all AIDS patients (77,127). In contrast, other possible viral agents, including HTLV-I, have been isolated in these patients at rates which indicate that exposure to these other viruses was only incidental and not related to AIDS (although some of these viruses may be the cause of specific diseases associated with AIDS). These results are being duplicated in countries around the world: the United States and France (154), France and Zaire (25,26), France (97), Britain (32,58), Denmark (103,104), Greece (118), Scotland (11), West Germany (9,71), and Japan (6).

A further indication of the causal relationship between HTLV-III and AIDS is the chronological association between the emergence of AIDS as a recognized disease and increasing exposure rates to HTLV-III among groups at high risk for AIDS. Among homosexual men attending a sexually transmitted disease clinic in San Francisco, for example, the proportion of patients with antibodies to HTLV-III increased from 1 percent in 1978 to 25 percent in 1980 and to 65 percent in 1984 (154).

Currently, antibodies to HTLV-III are found in approximately 75 to 90 percent of U.S. hemophiliacs, while percentages for hemophiliacs worldwide are 30 to 90 percent for Factor VIII users and 30 to 50 percent for Factor IX users (158). Since Factor VIII preparations from U.S. donors are used throughout the world, almost all studies have been done on patients receiving U.S. Factor VIII, at least in part. It is not clear that U.S. Factor VIII is a priori more infective than Factor VIII from other sources (160). However, in a study of Scottish and Danish hemophiliacs, 15.6 percent of Scottish patients, who were largely treated with Factor VIII concentrates produced in Scotland, versus 59.1 percent of Danish patients, who received both locally prepared concentrates and commercial concentrates made in the United States, were antibody positive to HTLV-III (105). In one longitudinal cohort study of hemophiliacs, no HTLV-III antibodies were detected prior to 1979 (from sera stored by a hematologist in Hershey, Pennsylvania). Subsequently, antibodies were first detected in 20 percent of sera collected during 1981 and 1982, and increased thereafter. By 1984, Factor VIII recipients had an overall positive rate of 74 percent, with 90 percent of frequent recipients of Factor VIII (at least twice a month) having positive antibodies (43,60).

Individual instances of a close correlation between HTLV-III and the development of AIDS have also been reported. For example, in one blood donor-recipient pair, both with AIDS, the virus was isolated from the donor's lymphocytes 12 months after he developed AIDS and from the recipient 1 month after she developed AIDS (47).

Other investigators have reported on three clinically healthy women intravenous drug abusers who were serologically positive for the virus and whose children developed AIDS, probably from transfer of the virus during pregnancy or the perinatal period (86).

Finally, studies in which chimpanzees were inoculated with serum and plasma from patients with AIDS or lymphadenopathy syndrome or with cultures of the virus have shown that chimps can be infected with HTLV-III (2,52,53,54). One chimp developed lymphadenopathy syndrome but no opportunistic infections, and the lymphadenopathy eventually disappeared (2,155). However, none of the chimps developed fulminant AIDS.

Thus, identification of HTLV-III as the basic causative agent for AIDS is now widely accepted by the scientific community, and current research is focusing on the relationship between exposure to the virus and development of the disease. Research on other possible causative agents has been refocused to examine the roles of these agents as "cofactors" in the causation of AIDS and of specific diseases associated with the syndrome.

HOW HAS THE PUBLIC HEALTH SERVICE (PHS) REDIRECTED ITS AIDS RESEARCH TOWARD HTLV-III WORK?

The discovery of HTLV-III has led to the rapid development of various methods to test for the virus's presence. The ability to grow HTLV-III in cell cultures plus the availability of tools from the field of molecular biology have made it possible to test people for the presence of antibodies to HTLV-III and for the presence of whole virus and fragments (antigens) of HTLV-III. Several diagnostic indicators for exposure to an infection with HTLV-III are identified below:

- *Presence of antibodies to HTLV-III.* Some tests for antibodies to HTLV-III use the whole virus as a source of antigens. Another approach is to fragment HTLV-III and use fragments to test for antibodies that may not be detected with whole virus preparations. Specific tests are now available to detect antibodies to the proteins that make up the "core" of the virus and to the proteins that make up the "envelope" (surface) of the virus. These core and envelope antigenic proteins are specific enough to HTLV-III that they can be distinguished from the core and envelope proteins of HTLV-I and HTLV-II (7,32,89,122). Differentiation between antibodies to core and envelope proteins is important to the question of whether specific types of antibodies can protect against the development of AIDS, as well as to the related question of whether an effective vaccine can be developed (to be discussed later).
- *Presence of antigens of HTLV-III.* The presence of HTLV-III and fragments of the virus in people can be tested by using sera from other people known to have antibodies to HTLV-III.
- *Presence of HTLV-III genes.* The techniques of molecular biology allow the construction of genetic probes that can be used to search through the cytoplasm and nuclei of cells suspected of being infected with HTLV-III (66). (As noted above, when HTLV-III in its DNA form is integrated into the chromosomes of an invaded cell, it is referred to as being in its "provirus" form.) These methods have been used to show the integration of HTLV-III into the genes of helper T cells and the presence of unintegrated HTLV-III DNA (66,134). Additionally, HTLV-III production by infected cells can be detected by very sensitive RNA hybridization methods so that individual infected cells can be visualized (68).
- *Culturing of HTLV-III.* With the successful in vitro culturing of HTLV-III, it is now possible to take cells and sera from people to see if HTLV-III can be isolated and directly grown (89,108,122).

These diagnostic indicators are being applied to studies on AIDS, some of which are enumerated below.

Blood Studies

In April 1983, soon after the first cases of blood-transfusion-related AIDS had appeared, blood banks and plasma collection centers implemented donor screening procedures to exclude members of population groups at high risk for AIDS. Prior to the announcement of the discovery of HTLV-III in April 1984, blood banks had been searching for "surrogate" laboratory tests that could be used to screen out blood that might transmit AIDS. Two of the tests that were considered were: 1) T4/T8 cell ratios because of the observation of lowered ratios in cases of AIDS and AIDS-related complex; and 2) the presence of antibodies to the core protein of the hepatitis B virus, because some of the groups (homosexuals, intravenous drug abusers) at high risk for AIDS also had a high risk for hepatitis B. The near availability of tests for detecting the presence of antibodies to HTLV-III has effectively made the usefulness of the search for surrogate tests of these types moot. Research grants sponsored by the National Institutes of Health (NIH) on surrogate tests have been reviewed and been reoriented toward cofactors research and/or toward the development of "second-generation" tests for HTLV-III (33).

Screening of blood donors will be undertaken through tests to detect the presence of antibodies against HTLV-III as proof of past exposure to the virus (174). This blood test will augment, but not replace, blood donor screening procedures currently in place to exclude members of groups at high risk for AIDS (40). One reason is that researchers now know that some people who have the virus in their blood have not developed antibodies to it and are also symptom-free (129).

Since a proportion of the tests that are initially positive will be falsely positive, all positive tests for antibodies to HTLV-III in the serum of blood donors will need to be confirmed. PHS has addressed this issue of test reliability in its recommendations for blood and plasma screening (see box 2-A). In addition to the question of the reliability of tests for detecting the presence of antibodies to HTLV-III, there is the question of what antibody positivity means. Other than revealing past exposure to HTLV-III, does it mean that these people carry the virus? Will they develop AIDS? Answers to these questions are not known at this time. (These questions on test reliability and significance are also at issue in obtaining the informed consent of persons who will be tested and are addressed in the "Related Issues" section near the end of this chapter.)

The high risk of AIDS in hemophiliacs was presumed to be due to transmission in Factor VIII concentrates, the assumption being that standard methods for preparing Factor VIII concentrates were not sufficient to inactivate a presumed viral agent. There have recently been developed newer methods of preparation that use heat treatment at a sufficient level to inactivate some viral agents in Factor VIII concentrates (there is a tradeoff in heat treatment between viral inactivation and preserving the biological activity of Factor VIII). With the discovery of HTLV-III, tests of inactivation of this specific virus could be conducted. Preliminary testing has shown that HTLV-III is very sensitive to heat and that recent methods of heat-treating Factor VIII concentrates are capable of inactivating the virus in vitro. These findings are being investigated further (42,156).

Other blood-related studies are discussed in the following section on epidemiologic work.

Epidemiologic Studies

Studies of different populations at risk for AIDS, their variations in associated risk factors and in clinical manifestations of AIDS, are of immediate relevance to our understanding of how the disease spreads, preventive strategies, and the possibility of early therapeutic interventions.

When AIDS was first recognized, tracking the development and spread of what was apparently a new disease had to be done without knowing what the cause of the disease was. Thus, it was necessary to survey specific illnesses—which were essentially limited to only one type of infection (*Pneumocystis carinii* pneumonia) and one type of cancer (Kaposi's sarcoma)—in the presence of immune suppression without known causes. This

Box 2-A.—PHS Recommendations for Screening Blood and Plasma Donations for Antibodies to HTLV-III

Initial Testing

Persons accepted as donors should be informed that their blood or plasma will be tested for HTLV-III antibody. Persons not wishing to have their blood or plasma tested must refrain from donation. Donors should be told that they will be notified if their test is positive and that they may be placed on the collection facility's donor deferral list, as is currently practiced with other infectious diseases, and should be informed of the identities of additional deferral lists to which the positive donors may be added.

All blood or plasma should be tested for HTLV-III antibody by ELISA [the name of the test procedure that is being used]. Any blood or plasma that is positive on initial testing must not be transfused or manufactured into other products capable of transmitting infectious agents.

When the ELISA is used to screen populations in whom the prevalence of HTLV-III infections is low, the proportion of positive results that are falsely positive will be high. Therefore, the ELISA should be repeated on all seropositive specimens before the donor is notified. If the repeat ELISA test is negative, the specimen should be tested by another test.

Other Testing

Other tests have included immunofluorescence and radioimmunoprecipitation assays, but the most extensive experience has been with the Western blot technique, in which antibodies can be detected to HTLV-III proteins of specific molecular weights. Based on available data, the Western blot should be considered positive for antibody to HTLV-III if band p24 or gp41 is present (alone or in combination with other bands).

Notification of Donors

If the repeat ELISA test is positive or if other tests are positive, it is the responsibility of the collection facility to ensure that the donor is notified. The information should be given to the donor by an individual especially aware of the sensitivities involved. At present, the proportion of these seropositive donors who have been infected with HTLV-III is not known. It is, therefore, important to emphasize to the donor that the positive result is a preliminary finding that may not represent true infection. To determine the significance of a positive test, the donor should be referred to a physician for evaluation. The information should be given to the donor in a manner to ensure confidentiality of the results and of the donor's identity.

Maintaining Confidentiality

Physicians, laboratory and nursing personnel, and others should recognize the importance of maintaining confidentiality of positive test results. Disclosure of this information for purposes other than medical or public health could lead to serious consequences for the individual. Screening procedures should be designed with safeguards to protect against unauthorized disclosure. Donors should be given a clear explanation of how information about them will be handled. Facilities should consider developing contingency plans in the event that disclosure is sought through legal process. If donor deferral lists are kept, it is necessary to maintain confidentiality of such lists. Whenever appropriate, as an additional safeguard, donor deferral lists should be general, without indication of the reason for inclusion.

Medical Evaluation

The evaluation might include ELISA testing of a follow-up serum specimen and Western blot testing, if the specimen is positive. Persons who continue to show serologic evidence of HTLV-III infection should be questioned about possible exposure to the virus or possible risk factors for AIDS in the individual or his/her sexual contacts and examined for signs of AIDS or related conditions, such as lymphadenopathy, oral candidiasis, Kaposi's sarcoma, and unexplained weight loss. Additional laboratory studies might include tests for other sexually transmitted diseases, tests of immune function, and where available, tests for the presence of the virus, such as viral culture. Testing for antibodies to HTLV-III in the individual's sexual contacts may also be useful in establishing whether the test results truly represent infection.

SOURCE: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, "Provisional Inter-Agency Recommendations for Screening Donated Blood and Plasma for Antibody to the Virus Causing Acquired Immunodeficiency Syndrome," *Morbidity and Mortality Weekly Report* 34:1-5, Jan. 11, 1985.

conservative "surveillance" definition of AIDS made it easier to identify populations at high risk, but it excluded other possible AIDS-related clinical conditions and probably underestimated the extent of AIDS.

The availability of various tests for HTLV-III should allow for a more accurate definition of AIDS and a more precise delineation of the natural history of the disease, clarifying whether antibodies that can protect against progression to full-blown AIDS exist and under what conditions a protective effect might occur. Use of the blood test for HTLV-III will also enhance epidemiologic studies of known high-risk groups such as homosexual and bisexual males with multiple sex partners, intravenous drug abusers, recent immigrants from Haiti, and hemophiliacs.

In the blood area, a large study supported by the National Heart, Lung, and Blood Institute (NHLBI) is focusing on immunologic consequences of transfusions. A component that has been added to the study deals with the collection and preservation of 200,000 serum samples from blood donors to be tested when the HTLV-III screening test becomes available (33). (There are 200,000 samples being collected on the assumption that the rate of HTLV-III-antibody-positive tests in the donor population will be approximately 0.5 percent, thereby yielding about 1,000 HTLV-III-antibody-positive donors.) The NHLBI-supported study will provide information on the extent of HTLV-III antibodies in the blood donor populations in cities in which AIDS is highly prevalent, as well as on the immunologic status of both donors with positive tests and recipients of their blood. The study should also provide important information on the natural history of exposure to HTLV-III in the blood donor and in the recipient following blood transfusion.

Identification of HTLV-III as the basic etiologic (causative) agent of AIDS has opened new avenues to epidemiologic studies of AIDS on a worldwide basis and has provided a plausible, though preliminary and controversial, explanation of the origins and spread of the disease from equatorial Africa to other parts of the world (12,120). AIDS cases in Africa have been found in epidemiologic patterns that differ from those in the United States, where AIDS is still occurring predominantly among homosexual and bisexual males. In Zaire, the male-to-female ratio of AIDS cases in one study was approximately 1:1 (120); and in a study in Rwanda, 9 of 17 patients were female (170).

HTLV-III is probably already prevalent in the general population of some African countries. In Uganda, antibodies to HTLV-III have been found in preserved sera collected in 1973 of 65 percent of 65 children of approximately 6 years of age (131), although there have not yet been any reported AIDS cases from Uganda. Sera collected in 1980 from 100 Zairian mothers used as a control group to compare HTLV-III-antibody-positivity with that of known AIDS patients were positive for HTLV-III in five cases, and at least one AIDS case may have occurred as early as 1977 (26). A study of female prostitutes in Rwanda has found approximately 20 percent to have antibodies to HTLV-III (16).

Finally, a study among 250 outpatients in a hospital in rural Zaire found that 12.4 percent had antibodies to HTLV-III (12). The presence of antibodies was higher in children than in adults. One researcher's hypothesis about the reason for the difference in positive antibody rates between the younger and older patients is as follows. When the older patients were younger, the incidence of positive antibodies among them and their peers was higher and probably similar to that of the younger patients. However, over the years, some of the older patients' peers with positive antibodies died of unrecognized AIDS, probably of opportunistic infections such as parasitic diseases, which would not have been distinguished from primary parasitic deaths in rural areas. A further hypothesis is that HTLV-III was probably endemic in rural areas and entered the urban population only recently with the immigration of persons from rural to urban areas. Alternatively, a related and cross-reactive virus that is distinct and does not cause AIDS could account for their rural pattern of antibody positivity (16).

Another factor to consider in searching for the origins of AIDS is that HTLV-III has been shown to be more similar morphologically and by the nucleotide sequence of its genes to an animal retrovirus known as "visna" virus than it is to the other two members of the HTLV family, HTLV-I and HTLV-II (63). Visna virus causes a chronic degenerative disease of the central nervous system in sheep and belongs to a subfamily (Lentiviruses) of retroviruses that infect ungulate (hoofed) mammals, particularly domestic sheep, goats, cattle, and horses. (Findings described earlier that HTLV-III can infect the brain (135) provide further evidence of a relationship between HTLV-III and the Lentivirus subfamily of retroviruses.) Thus, HTLV-III might have been initially transmitted from domestic ungulates, and the epidemiologic evidence from central Africa provides a clue as to when and where that initial transmission might have taken place.

The contribution of a number of cofactors—i.e., factors or agents which are necessary for or which increase the probability of the development of disease in the presence of the basic etiologic agent of that disease—to the actual development of AIDS is also being investigated in epidemiologic and other studies. Results of animal studies and studies of the prevalence of HTLV-III antibodies and virus in humans suggest that not everyone exposed to HTLV-III virus develops fulminant AIDS. Thus, it is assumed that other factors may play a role in making people susceptible to development of the disease, primarily through alterations of the immune system. There are a number of hypotheses about what these risk factors might be. Factors currently under investigation in U.S. populations include the following (8,35,95,110,138,165,173):

- presence of cytomegalovirus;
- presence of Epstein-Barr virus;
- presence of other herpes viruses;
- exposure to hepatitis;
- iatrogenic effect of steroids and other medicines (e.g., psychoactive drugs);
- use of alcohol and other recreational drugs (e.g., heroin, cocaine, marijuana, methadone);
- cigarette smoking;
- antigenic stimulation as a result of various sexual practices;
- ethnicity;
- particular underlying diseases; and
- psychosocial risk factors (e.g., life satisfaction, self-esteem, depression, coping mechanisms, sense of control, social support, stress).

The resources that PHS is devoting to the investigation of cofactors are discussed below in the section entitled "How Adequate Are PHS's Resources Devoted to AIDS?"

Treatment Protocols

The development of effective treatments for AIDS is urgent, as there is already a serious worldwide epidemic. By the end of 1984, the total number of U.S. AIDS cases that had been reported to the Centers for Disease Control (CDC) was approximately 7,000; and the number of reported cases has been doubling every year—almost 900 cases prior to December 1982, more than 2,000 cases in 1983, and about 4,000 cases in 1984. Seventy-three percent of AIDS patients diagnosed before January 1983 have died (157). Furthermore, extrapolations from trends in the incidence rate of AIDS (67) suggest that an additional 40,000 new cases can be expected in the United States in the next 2 years (125). There have already been over 500 cases in the rest of the Americas, 600 in Europe, and several thousand in central Africa (125).

Approaches for treating patients with AIDS include the following:

- treatment for opportunistic infections and cancers;
- reconstitution of the immune system through bone marrow transplants and lymphocyte transfusions;
- immunologic enhancement with T-cell growth factor (TCGF), interferon, and immunoregulatory agents such as isoprinosine and imuthiol; and
- agents directed against the HTLV-III virus itself (84).

Prior to the discovery of HTLV-III, treatment was directed at the specific opportunistic infections and malignancies associated with AIDS. Treatment of the immune deficiency itself proceeded along two fronts: 1) attempts to restore immune functions; and 2) the use of known antiviral agents, on the presumption that the epidemiologic pattern of AIDS pointed to an infectious agent, most likely a virus.

Although the discovery of HTLV-III has not affected treatment protocols for associated opportunistic infections and malignancies, it has affected treatment protocols for the underlying immune deficiencies associated with AIDS. Early treatment methods for immune deficiency involved the use of general antiviral agents (e.g., gamma interferon) and attempts to restore immune functions through methods such as lymphocyte transfusions and administration of TCGF (also known as interleukin-2). These "shotgun" methods were not successful. Which antiviral agents would be effective and when they should be administered were not known. The timing of the administration of antiviral agents is probably crucial since they may have to be administered before HTLV-III invades cells. Lymphocyte transfusions were analogous to pouring water in a leaky bucket (since the virus would destroy these cells), and TCGF stimulated T cells, a condition now known to enhance T-cell infectivity by HTLV-III.

With the discovery of HTLV-III, more specific therapeutic approaches are now possible. First, the availability of HTLV-III cell cultures makes possible an in vitro test of possible anti-HTLV-III drugs. One such drug, suramin, has been shown to protect T-lymphocyte cell cultures against the cytopathic effects of HTLV-III through inhibition of the reverse transcriptase of HTLV-III (23) and is undergoing limited clinical trials at NIH. Another drug, ribavirin, a general antiviral agent, has also been shown to inhibit HTLV-III in vitro (99). Finally, French investigators report that they have tested another chemical, HPA-23 (heteropolytungstate, an inorganic cryptate), which inhibits the reverse transcriptase enzyme of murine (mouse) retrovirus in vitro and in vivo. Four patients, three with AIDS and one with lymphadenopathy syndrome, have been treated with HPA-23, and virus replication has been inhibited, though not completely (106).

Strategies directed at the virus itself can also encompass more than inhibition of reverse transcriptase activity. Eventually, it might be possible to use antibodies against HTLV-III to prevent or modulate infection (passive immunization). Moreover, since HTLV-III invades cells, antibody infusions will probably have to be used before or at the time of initial infection, perhaps in conjunction with a vaccine to confer more permanent immunity (if such a vaccine proves possible). When passive immunization would be most propitious is not known, but the epidemiologic studies now under way may eventually answer this question. Another possibility would be to couple toxins with antibodies against HTLV-III.

Approaches directed at disrupting HTLV-III's life cycle might take place at the following points: 1) binding of the virus to the target cell surface, 2) entry into the cell, 3) transcription of RNA to DNA (the target of reverse transcriptase inhibitors), 4) integration of the virus into the cell's genes, 5) transcription of DNA to RNA (in preparation of the virus's replication and release from the cell), 6) transfer of the virus to the cell surface, and 7) disruption of the cell and release of the virus (180). Studies described earlier, which showed that the T4 molecule on T4 lymphocytes was necessary for HTLV-III to infect the cell, used monoclonal antibodies against the T4 molecule to see if binding of HTLV-III to the T4 lymphocyte would be blocked (39,81). This blockage was in fact shown and might constitute a possible method of inhibiting infection by HTLV-III. Whatever the mode of attack against the virus, successful therapy depends on whether or not infected cells die in a short period of time and on whether there is a regenerative capacity of T cells. It is not realistic to expect that all of the virus will be eradicated. Therefore, the hope is that the immune system can handle a minimum of infection, and lifetime treatment against the virus may be needed (180).

Finally, attempts at reconstitution of the immune system (85) may be more successful if done in conjunction with specific agents against the HTLV-III virus.

Animal Models

Chimpanzees have been successfully infected with the AIDS virus and have developed immunologic abnormalities and lymphadenopathy, but no opportunistic infections or tumors characteristic of AIDS (2,52,53,54,155). Other possible animal models are being screened by testing for the effect of HTLV-III on the animals' T lymphocytes in cell cultures.

At NIH, prior to the discovery of the AIDS virus, three chimps were sequentially infused with plasma from three different patients with lymphadenopathy syndrome, Kaposi's sarcoma, and life-threatening opportunistic infections, respectively. Two chimps developed antibodies to HTLV-III (specimens were stored and subsequently tested when an HTLV-III test became available), and one of the two chimps developed a transient severe lymphadenopathy 26 weeks after inoculation, which persisted until 58 weeks after inoculation (2). At CDC, two chimps were inoculated with concentrated HTLV-III and autologous lymphocytes that had been infected in vitro. The virus has been found to grow and persist in the chimpanzees' lymphocytes, and the chimps have produced antibodies to the virus; however, neither chimp has developed any clinical illness or lymphadenopathy (52). In another study using tissues and plasma from AIDS patients, chimpanzees were similarly infected and antibodies produced. Infection and antibody production also occurred in chimps inoculated with whole blood from chimps previously infected and shown to have produced antibodies. Except for one infant chimpanzee which died 5 months after inoculation (cause of death under investigation), all 23 of the inoculated chimps have remained clinically well for periods of between 2 and 15 months (53,54). These chimpanzee inoculation studies, in addition to having promise as an animal model, may indicate that AIDS is not an inevitable consequence of HTLV-III exposure or even infection.

Primates other than chimpanzees, including rhesus, stumptailed, cynomolgus, and bonnet macaques, the capuchin, the squirrel monkey, and the patas monkey, have also been inoculated with HTLV-III. Rhesus monkeys have recently been shown to undergo infection by HTLV-III, but have not produced antibodies and have remained clinically well (48,53,54). Other animal species that might serve as animal models are being screened before inoculation studies are initiated. Lymphocytes provided by the National Institute of Allergy and Infectious Diseases (NIAID) from 25 animal species are being studied in cell cultures by NCI to see if they can be infected by the virus. In the case of those which are successfully infected in vitro, the animals themselves will be inoculated (121).

WHAT ABOUT EFFORTS TO DEVELOP AN AIDS VACCINE?

In general, "live" vaccines produce better immunity because of prolonged stimulation from viral reproduction. Noninfectious "inactivated" vaccines, on the other hand, require frequent booster shots. Noninfectious vaccines can be made either from whole inactivated organisms or from parts ("subunits") of the organism that have antigenic properties which stimulate immunity. Neither live virus vaccines for AIDS nor whole inactivated preparations containing the genetic material of the AIDS virus currently hold much promise: 1) because it is not known what constitutes an "inactivated" virus in the case of HTLV-III; and 2) because the genetic structure of HTLV-III contains segments that may cause cancer by activating normal cellular genes involved in the initiation of tumors. Thus, only "subunit" vaccines against AIDS are under serious investigation, albeit through a variety of methods including the use of live viruses other than HTLV-III.

When a foreign organism invades the body, several different antibodies are produced, each directed at specific subunits of the organism that the body's immune system recognizes as different antigens. Only some of these antibodies will be directed at subunits of the organism that are crucial to the organism's life cycle. "Subunits" that stimulate the production of *neutralizing* or *protective* antibodies are necessary to produce an effective vaccine. Such subunits are usually the proteins that make up the "envelope" (external coat), as opposed to the "core" of the virus. One way to determine which antigenic subunits may produce a protective antibody response is to produce antibodies against individual antigenic subunits and determine whether these antibodies neutralize infectious virus in cell cultures (in vitro testing).

The three-dimensional structure of a viral antigen is probably crucial for eliciting the proper antibody response; i.e., without the proper three-dimensional configuration of the viral antigen as it appears on the whole virus, antibodies would be produced against a viral subunit, but might not "fit" the viral antigen as it actually appears on the whole virus and therefore might not inactivate the virus. After they are synthesized, envelope proteins have carbohydrate molecules attached to them which help to determine their three-dimensional structure. (This modification is referred to as "post-translational modification," and the attachment of a carbohydrate molecule to the protein molecule is called "glycosylation.") Thus, HTLV-III subunit proteins produced for use as vaccines may need to be glycosylated or treated by some other method to approximate the three-dimensional configuration of the virus's original subunit.

Relevant to the possible development of a vaccine to protect against HTLV-III is the experience with a vaccine against feline leukemia virus. Feline leukemia virus attacks T cells in cats and can cause either immunosuppression or cancer. There are three subgroups of the virus, one of which does not occur naturally but develops in cell cultures when either of the two naturally occurring types is cultured. All three subgroups produce an envelope glycoprotein of the same molecular weight (gp70), but each subgroup's glycoprotein is structurally distinct from the others.

The first experimental vaccines for feline leukemia virus used either the inactivated viruses themselves or the T-cell tumor cultures infected with the viruses. Both types resulted in immunosuppression in cats because of the presence of p15E (an envelope protein with a molecular weight of 15,000). Another feline leukemia vaccine was developed by altering the culture medium in which the virus-infected T cells were grown; the incomplete viruses or fragments that resulted proved to be about 90 percent protective against the virus in cats themselves. The envelope proteins produced by this method were: 1) the gp70s of the three subgroups of feline leukemia virus, which neutralized the virus in vivo and prevented viremia; and 2) another protein (FOCMA, or feline-oncornavirus-associated cell membrane antigen) formed by lymphosarcoma cells infected with the virus, which prevented solid tumor formation. FOCMA may be identical to or immunologically similar to the gp70 of the nonnaturally occurring subgroup of the feline leukemia virus. Field trials of this subunit feline leukemia vaccine are being completed, and the vaccine may be available sometime in 1985 (44).

Experience with the subunit feline leukemia vaccine is relevant to the development of an AIDS vaccine because: 1) HTLV-III may contain subunits that may be detrimental to the patient; and 2) if there is a subunit that elicits protective antibodies, it is likely to be a high molecular weight envelope glycoprotein. Of the several protein subunits in HTLV-III, natural human HTLV-III antibodies predominantly recognize an antigen of 41,000 molecular weight (p41). This observation has led to opposing preliminary conclusions by researchers. On one hand, some researchers have suggested that p41 may be of use for prophylactic measures in persons at risk for AIDS (71). However, antibodies to p41 can be found in all AIDS cases, even when different isolates of the HTLV-III virus have been identified. Antibodies to p41 may therefore be a good diagnostic indicator of infection with HTLV-III, but p41 may not be the antigen for vaccine development. Another suggestion, therefore, is that a more specific antigen needs to be identified and that places to look for antibodies might include lymphadenopathy patients who get better; selected long-term partners of AIDS patients who are well; hemophiliacs, many of whom have high positive titers of antibodies to HTLV-III; and patients with only Kaposi's sarcoma and no opportunistic infections (48).

NIH has taken the lead in developing an AIDS vaccine, at both NCI and NIAID. NIAID would usually be the primary institute involved in vaccine development, but in the case of AIDS, NCI has the most experience with human retroviruses. Vaccine development is being pursued both intramurally and through extramural funding of non-Federal researchers.

NIH is conducting both supportive and direct activities related to vaccine development (55). Supportive activities include: 1) large-scale production of HTLV-III to characterize its various antigens and immunogenic properties (and to provide adequate quantities of virus for other activities); and 2) isolation and characterization of the virus's envelope proteins. Related activities include the development of an animal model to test the efficacy of future vaccine candidates, as well as epidemiologic and serologic investigations of the natural history of AIDS to determine whether or not protective antibodies exist, when in the natural history of AIDS such antibodies appear, when a vaccine would have to be given, etc. Several activities directed at vaccine development at NIH are discussed further below.

Subunit Vaccine From Cultured Virus

Viral proteins can be produced either by breaking up whole virus or by changing the conditions under which the virus is grown so that greater amounts of specific viral fragments may be preferentially produced. The latter technique has been used to produce a new subunit vaccine against feline leukemia virus and could be used to produce an AIDS vaccine. The feline leukemia vaccine and associated hazards were discussed above.

Recombinant DNA Vaccine

An alternative to using whole virus as a source of a subunit vaccine is to use recombinant DNA techniques to make a vaccine. Once the gene(s) for the viral protein(s) is identified, it is (they are) cloned and inserted into bacteria, yeast, or mammalian cells, which then produce the protein(s).

The genes for several proteins (p41, p55, and p54) of unknown specificity from at least three different isolates of HTLV-III have already been cloned and inserted into bacteria and yeast (55). One hypothesis is that the glycosylated envelope proteins gp120, gp100, and gp46 are the most likely candidates for an AIDS vaccine (74).

Mammalian cells and, to some extent, yeast cells (but not bacterial cells) have the ability to glycosylate (add carbohydrate molecules) to these proteins and are the favored method of synthesis for subunits that need post-translational modification. (The Merck Institute for Therapeutic Research at West Point, Pennsylvania, for example, is close to licensing a vaccine for hepatitis B that uses yeast-cloned hepatitis B virus surface antigen (101), and Biogen plans to begin human clinical trials for a similar vaccine in early 1985 (13).)

A related method of preparing an AIDS vaccine would be to synthesize the viral proteins directly, based on the nucleotide sequences of their genes. It is now known which nucleotide sequences code for each of the 20 amino acids from which all proteins are made. To obtain the proper three-dimensional configuration, however, glycosylation or other methods would probably be needed.

Infectious Recombinant Vaccine

If the gene(s) coding for the proper subunit of HTLV-III could be inserted into other viruses that are not harmful to humans, these viruses themselves could then be used in vaccinations. The result would be a live vaccine with more sustained antibody production than an inactivated vaccine but without the hazard of using live, whole HTLV-III virus for continual stimulation of antibody production.

The vaccinia virus (which has long been used to vaccinate against smallpox) has already been used for the insertion of genes from a number of viruses and one parasite, including hepatitis B (111,137), rabies (78), herpes simplex, influenza viruses, and malaria. The recombinant vaccinia virus has been shown to be capable of producing rabies virus glycoprotein; i.e., following insertion of the gene for the rabies envelope protein, the vaccinia virus (which propagates in the cytoplasm of infected cells rather than in the nucleus) not only can produce the rabies envelope protein but also adds carbohydrate molecules to the protein, resulting in production of a rabies glycoprotein that produces protective antibodies (78). Some of these infectious recombinant vaccines have been tested in animals but not in humans.

Much of the work on recombinant vaccinia virus has been done by researchers at NIAID and their collaborators, and work with HTLV-III genes in vaccinia virus is being conducted through NIAID. Meanwhile, NCI has also issued requests for proposals for the development of human recombinant viruses other than the vaccinia virus. One reason is that many people have been previously exposed to the vaccinia virus through smallpox vaccinations, and if revaccinated with an HTLV-III-gene-containing vaccinia virus, their antibody-producing responses would be short (anamnestic rather than primary responses). Possible alternatives to the vaccinia virus are the adenoviruses, and NCI reports that William Jarrett, the discoverer of feline leukemia virus, is interested in examining antibody production in dogs with a dog adenovirus in which HTLV-III genes would be inserted. Another possibility would be to use herpes viruses (48).

Anti-Idiotype Vaccine

Contact between an antigen and an antibody can be envisioned as a precise fit between two pieces of a three-dimensional puzzle. If a second antibody were made against a particular antigen's antibody (the "idiotype"), the second antibody (the "anti-idiotype") would have a part that mimics the part of the antigen that was in contact with the first antibody. And if the first and second antibodies came from the same animal species, they would differ only in that part which comes in contact with the antigen; the rest of the molecules of these antibodies would be identical. Therefore, the anti-idiotype, when used as a vaccine in the animal species from which it was derived, would elicit an antibody response only to that part which was identical to the original antigen.

In addition to the specificity of the elicited antibody response, the fact that this anti-idiotype vaccine would consist mostly of a molecule that would be recognized as "self" would mean that it would not be removed from the body as quickly as it would be if the antibody had come from another animal species. Therefore, if such a vaccine were made with human monoclonal antibodies, it would be present in the body for a longer period and produce more of an immune response. Furthermore, since no part of the anti-idiotype would have been made from the actual virus (either from the whole virus or from its genes through recombinant DNA methods), there would be no possibility of infection from the virus or its products.

An experimental anti-idiotype vaccine has been developed in mice against reoviruses (another family of RNA viruses), and the researchers are now applying their methods to HTLV-III (182). Successful immunization of mice against the bacterium *Streptococcus pneumoniae* with an anti-idiotype vaccine has also recently been reported (100).

Prospects for a Successful Vaccine

A subunit vaccine, made through purification from whole virus, special culturing techniques, or through the use of recombinant DNA technology is the most likely vaccine candidate to be first available. However, it is not known at this time whether an effective vaccine against HTLV-III can be made. The virus has only recently been discovered, and investigations into the relationship of the natural history of the disease with specific immunologic responses, which may answer the questions of whether or not protective antibodies exist and under what circumstances, have just begun.

An additional question for vaccine development is the variation among the different isolates of the HTLV-III. In contrast to HTLV-I, which has been found to have only a few minor variations despite its worldwide distribution, HTLV-III isolates have been found to have many variations. Variations have been observed in the sequences of the nucleotides that make up the genes (1,23,66,91). These imply either a large number of subtypes or the possibility of sequential mutations analogous to some animal retroviruses. As noted earlier, HTLV-III is related to visna virus, an encephalitis-inducing retrovirus of sheep, which can change its envelope proteins antigenically (63). On the other hand, no heterogeneity has been seen so far in a given HTLV-III isolate, nor has heterogeneity developed in culture. Most of the heterogeneity is seen in the genes coding for the envelope proteins, and it is not yet known whether the genetic heterogeneity results in significant antigenic differences (178).

An emerging issue is the question of who might benefit from a vaccine. Testing of high-risk groups for exposure to HTLV-III has shown a rapid increase in the percentage of persons exposed—up to 65 percent for some groups of homosexual and bisexual males (154), nearly 90 percent in some intravenous drug abusers (141), and up to 90 percent of hemophiliacs who regularly use Factor VIII concentrates (43,60,79). On the other hand, cases of heterosexual transmission and transmission between family members are being reported (28,86,126), and the disease transmission pattern in central Africa appears different from that in the United States, with relatively more female patients in central Africa and significant rates of the presence of antibodies to HTLV-III in the general central Africa population (12,120,170). Furthermore, since HTLV-III has now been isolated from semen and saliva (65,73,181), the population at risk may change or may include more groups those than currently identified in the United States.

One way that AIDS may get into the general population is through female prostitutes. Seventeen of sixty-five AIDS cases not known to belong to any risk group are now known to have had frequent contact with prostitutes. There are approximately 200,000 drug abusers undergoing treatment in public clinics at any one time, totaling about 400,000 over the course of a year. This number excludes about 1.5 million drug abusers who are in private treatment or who are occasional users. About 20 percent of female drug abusers resume drug use within 1 year after treatment in methadone clinics, and about 31 percent of female drug abusers admit to prostitution. Thus, female drug abusers are habitual users and many are very active sexually (in part to support their addiction). U.S. cities with large numbers of drug abusers and where AIDS is most prevalent include New York, Miami, San Francisco, and Los Angeles, which are also popular tourist areas, hence intensifying the probability of spread through female prostitutes (62).

Finally, there is the question of the private sector's interest in developing and marketing an AIDS vaccine. There has been great interest by the private sector in developing and marketing blood tests for HTLV-III, but the technical difficulties involved in developing and producing an effective and safe vaccine, and product liability issues concerning vaccine-related injuries may make an AIDS vaccine much less attractive commercially than the markets for screening and other diagnostic tests for AIDS. Although the private sector seems interested in all AIDS-related products, it remains to be seen whether the interest generated in the marketing of a blood test will carry over into the vaccine area. If an AIDS vaccine proves feasible, the Federal Government may need to assume production activities in addition to the developmental activities it is currently undertaking.

HAS THE DISTRIBUTION OF NEW INFORMATION AMONG RESEARCHERS AND REGULATORS BEEN ADEQUATE AND TIMELY?

Whether information about AIDS has been generated and disseminated on an adequate and timely basis has been an issue of recurrent concern. As the new syndrome, later to be called AIDS, began to surface, there was relatively fast coordination and dissemination of information among PHS agencies and outside researchers. In September 1981, only 6 months after the first clusters of an unusual syndrome involving Kaposi's sarcoma and *Pneumocystis carinii* pneumonia were reported to CDC, NCI and CDC cosponsored a workshop on AIDS at which a significant amount of information about the syndrome's epidemiology and virology was shared with 50 intramural and extramural participants (164). In the intervening months, CDC, NCI, and NIAID researchers had begun to reorient some of their intramural research, and the first patients with the syndrome had been admitted into NIH's Clinical Center.

Since 1981, individual researchers and PHS agency managers have coordinated the dissemination of information about AIDS in a variety of ways. PHS units other than CDC, NIAID, and NCI began to be involved as more became known about the disease. Most, if not all, of the PHS institutes and agencies have had internal working groups or committees meeting on AIDS with varying levels of intensity depending on research developments. In addition, there have been numerous interagency meetings and conferences on AIDS, attended by PHS researchers and PHS-funded grantees. The Assistant Secretary for Health, PHS, arranged for journals to expedite their review process so that AIDS research results could be published more quickly. NIAID took the lead in publishing the *AIDS Memorandum*, a compilation of nonreviewed research on AIDS, and an AIDS bibliography to speed up the dissemination of information to researchers. Furthermore, interagency task forces have worked on developing recommendations on blood donation (153) and on the blood test for HTLV-III (159).

At the PHS management level, former Assistant Secretary for Health Edward Brandt established a PHS Executive Committee on AIDS in May 1983 (21). The committee was chaired by an individual from CDC (not chosen to be a CDC representative per se) and had representatives from all five PHS agencies: CDC, NIH, the Food and Drug Administration (FDA), the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), and the Health Resources and Services Administration (HRSA). The committee's function was to coordinate PHS efforts, but in practice, the committee served primarily as a way in which PHS's central management was apprised of progress in AIDS research.

With the announcement of the findings of NCI's work on HTLV-III in April 1984, Assistant Secretary Brandt reconstituted the PHS Executive Committee into the AIDS Executive Task Force, chaired by him, for the following purposes:

- to develop and implement a strategy for PHS efforts in AIDS;
- to determine and allocate the resources required to accomplish the strategy; and
- to develop policies and procedures for informing the public, Congress, and the scientific community about PHS's efforts.

Three panels were established to accomplish these purposes: 1) a science panel, 2) a resources panel, and 3) an information panel (18). In September 1984, four specific task forces were also established: 1) one on vaccine development and therapeutic intervention, chaired by the Director of NIH with representatives from NIH, CDC, and FDA; 2) one on epidemiology and prevention, chaired by the Director of CDC with representatives from CDC, NIH, FDA, and ADAMHA; 3) one on blood and blood products, chaired by the Director of FDA's Center for Drugs and Biologics with representatives from FDA, NIH, CDC, and ADAMHA; and 4) one on psychological, psychiatric, and addictive aspects, chaired by a representative from ADAMHA with representatives from ADAMHA, NIH, CDC, and FDA. The Science Advisor to the Assistant Secretary for Health was designated the PHS coordinator of these task force activities. The Science Advisor also coordinates the private sector production of the blood test for HTLV-III and chairs committees concerned with animal studies, bioethics, and biosafety, and the utilization of the blood test (21).

The PHS task forces and committees continue to meet on a regular basis. Since the discovery of the probable AIDS etiologic agent, formal information-sharing activity on a management level has increased substantially, and centralized coordination of activities is also on the increase. Members of the Epidemiology and Prevention Task Force not only have agreed to distribute articles prior to publication, but have also agreed to discuss studies at the planning stage (96) in order to avoid unnecessary redundancies and to ensure that all the necessary areas are being covered. The Task Force on Psychological, Psychiatric, and Addictive Aspects is discussing participation by the National Institute of Mental Health (NIMH) in the NHLBI study of blood donors (138). As before, however, information sharing among individual laboratories and researchers continues both formally (e.g., HTLV Symposium, Dec. 6-7, 1984 (161)) and informally.

The Office of Technology Assessment (OTA) has identified five factors which may have impeded the generation and dissemination of new information about AIDS. First, NCI has not fully shared HTLV-III supplies with CDC, perhaps slowing the comparison of LAV and HTLV-III. Second, the announcement by the Secretary of the Department of Health and Human Services (DHHS) Margaret Heckler of NCI's discovery of HTLV-III provided overly optimistic assessments concerning the usefulness of a blood test and prematurely committed the Federal Government to require use of the test for antibodies to HTLV-III in blood and plasma collections. Third, in the context of a public health emergency, the grant application and approval process for extramural research works slowly. Fourth, Federal regulations covering commercial development of drugs, biologics, and devices mean that much information is not subject to full public scrutiny. Finally, the coordination of PHS resources could be improved, as discussed in the section below entitled "How Adequate Are PHS's Resources Devoted to AIDS Prevention and Treatment?"

NCI and CDC Sharing of HTLV-III Culture Samples

At about the same time that the Assistant Secretary for Health established the first PHS Executive Committee on AIDS in May 1983, the Director of NIH established an NIH Coordinating Committee. Part of the reason for establishing the NIH Coordinating Committee was that CDC and NIAID were collaborating with the French researchers who had just published findings implicating a new virus they called "lymphadenopathy-associated virus" or LAV (7) as the cause of AIDS, but neither CDC nor NIAID was aware of similar work that had been going on in NCI's Laboratory of Tumor Cell Biology under Dr. Robert Gallo (179).

CDC had received samples of LAV from the French researchers in May 1983 (the month in which their findings were published) and again the following month, but had not been able to culture it. In February 1984, CDC again received the virus from the French researchers, and this time, CDC was able to culture it (38). In late April 1984, DHHS Secretary Heckler announced the discovery of HTLV-III and prospects for a blood test and vaccine (70). Gallo and his coworkers had their results published in May 1984 and sent CDC their cultures later that month. CDC had difficulty growing the cultures in bulk and asked for more culture materials from the PHS Science Advisor, who was coordinating the production of the blood test for HTLV-III and arranging for transfer of large amounts of HTLV-III cultures to the commercial companies who would develop the blood test. Subsequently, CDC was given a small, but in its view insufficient, additional amount. At the end of 1984, CDC signed a purchase agreement with NCI for 100 liters of material (38).

One consequence of CDC's use of the French instead of the NCI virus cultures was that the research papers published by CDC and their collaborators, in which evidence of the AIDS virus was presented, referred to "LAV" instead of to "HTLV-III." This situation might have been avoided, and comparisons of the "LAV" and "HTLV-III" isolates might have taken place sooner, if PHS had arranged for sharing of NCI culture materials with CDC with as much attention as PHS has given to transferring bulk quantities of the cultures to the five commercial firms developing blood tests for AIDS under NCI's license.

DHHS Announcement of the Discovery of HTLV-III

The announcement by DHHS Secretary Heckler in April 1984 of the discovery of HTLV-III was a dramatic and extremely positive assessment of the implementation of NCI's research into the HTLV-III virus (70a). The announcement called AIDS "a disease with two names," the other name being "Fear," announced that an "arrow" had been aimed and fired at AIDS and had hit the target "only two or three rings away from the bulls-eye," and concluded that "(y)et another terrible disease is about to yield to patience, persistence and outright genius."

Secretary Heckler's announcement indicated that a blood test could be widely available within about 6 months and that a vaccine might be ready for testing in about 2 years, and most attention has focused on these two developments. In addition, however, Secretary Heckler committed the Federal Government to the use of the blood test in screening blood and plasma donations. The Secretary's announcement indicated that the blood test could "identify AIDS victims with essentially 100 percent certainty" and thus should prevent transfusion-related AIDS, including AIDS in hemophiliacs. The announcement also indicated that the blood test would allow prompt and early diagnosis of people who may have been infected by HTLV-III.

In trying to reassure the public of progress against AIDS, Secretary Heckler appears to have been too optimistic regarding the use of the blood test to screen for possible AIDS carriers. The Secretary's announcement also did not take into account the social implications and ethical dilemmas that would have to be addressed when persons who might be carriers of HTLV-III were identified through a blood test.

As mentioned earlier in this memorandum, it is now known that the blood test for antibodies to HTLV-III will not detect all persons exposed to the virus, because some persons who have the virus in their blood do not produce antibodies and can also be symptom-free (129). Furthermore, studies of hemophiliacs for antibodies to HTLV-III have shown that most hemophiliacs have already been exposed to HTLV-III (43,60); thus, only new hemophiliacs (and the minority of present hemophiliacs not yet exposed) will benefit from blood and plasma screening.

Aside from these limitations of the blood test are the difficult issues of what to tell persons who are found to have antibodies to HTLV-III and who should have access to lists of HTLV-III antibody-positive persons. In July 1984, the New York State Council on Human Blood and Transfusion Services advised the New York State Health Commissioner that mandatory testing of blood donors for viruses associated with AIDS was premature (114). Following this action, the five-member New York City Board of Health, in a resolution approved unanimously on October 17, 1984, recommended that the blood test be given only in the context of controlled research programs which preserve the confidentiality of participants (113a). The Board of Health noted that although the test "provided the opportunity for great scientific strides," unanswered questions mean that the test carries a "threat of mental anguish for those who receive the results." These issues do not seem to have been raised and addressed prior to Secretary Heckler's announcement in April 1984.

Funding of Extramural Research

Another coordination issue is whether or not NIH funding of extramural research on AIDS could have taken place more quickly. The policy question here is not so much whether extramural funding of specific research areas was tardy within the time frame of established processes, but whether the usual processes through which extramural research is funded can and should be accelerated in public health emergencies.

NIH research grants take about 16 months from conceptualization to awards, and contracts take about 14 months. The first round of extramural grants awarded by NCI/NIAID was funded through cooperative agreements (which have been used only in the last 2 years), in which researchers from the funding agency participate to some extent in the research activities for better control of the studies. Almost immediately after the NCI-CDC workshop on Kaposi's sarcoma, NCI's Division of Cancer Treatment, together with NCI's Clinical Division and NIAID, began to develop requests for applications (RFAs) to investigate multiple aspects of AIDS. These RFAs were developed and funds set aside during the first half of 1982, and the RFAs issued in August 1982. Proposals were received in October 1982, and awards were made beginning in January 1983. A second round of RFAs was issued by NCI and NIAID in May 1983, directed at biological agents in AIDS. These RFAs were awarded in March 1984, at about the time (April 1984) that the announcement of the discovery of HTLV-III was made by DHHS Secretary Heckler. (All grantees were contacted to make sure they were aware of Gallo's findings (29)). Thus, these grants took a total of 14 months, in part because of negotiations with the Office of Management and Budget (OMB) over the specific language used in the agreements (29).

Some steps have been taken to speed up the normal process. For example, mail ballotting has been used instead of face-to-face meetings by reviewers. Or researchers working in relevant areas have had their grants (or contracts) augmented to direct their ongoing research specifically at the AIDS problem. Nevertheless, a period of at least several months is probably still necessary to fund new research projects, given the time needed to conceptualize the problem in researchable terms, to review the work statements, including outside experts such as an institute's advisory body, to allow respondents adequate time to develop and write their proposals, and to evaluate and rank each proposal. In addition, the more the usual process is shortened, the more serious will be concerns over the quality (and therefore, usefulness) of the research activities funded. Nonetheless, the extramural grants process for AIDS research was not significantly accelerated over the usual grants process, and the process needs to be examined to see if bureaucratic processes can be streamlined without compromising the quality of research that is funded.

Federal Policy on Commercial Development

The general policy in this country is to leave the commercial development of technologies, including technologies derived from Federal biomedical research, to the private sector. Once under commercial sponsorship, research and development activities are considered proprietary and will not be made public unless voluntarily released. Under the Federal Food, Drug, and Cosmetic Act, this restriction applies when the sponsor of a new drug has applied to FDA for Investigational New Drug (IND) status to conduct clinical investigations. Thus, for example, FDA cannot divulge even the protocols being used by the five companies under license from NCI to develop AIDS screening tests to Federal researchers not directly involved in these activities; FDA is also enjoined from discussing when such trials will be completed and marketing approval granted. Federal researchers, on the other hand, will generally share their research, including their research materials, their primary concern being the qualifications of the private researchers and the quality control processes they have established (e.g., whether or not their laboratory facilities meet standards for containment of infectious agents).

In the case of AIDS, the sharing of information developed by commercial firms was enhanced in small part because PHS selected the companies that would get the HTLV-III culture developed in the NCI laboratory. Thus, for example, Dr. Gallo met with the five companies soon after they received the materials to discuss their use. However, other laboratories have cultured the virus and sold or given it to companies other than the five selected by PHS, and the status of those companies' activities is formally unknown to any Federal researcher except at FDA. As an illustration, a company (Cellular Products of Buffalo, New York) not among the five licensees of NCI may be among the first companies to market an HTLV-III test; and another company (Centocor of Malvern, Pennsylvania) claims to be the first to successfully express polypeptides (small proteins, presumably antigenically similar to proteins of HTLV-III) specific to antibodies to HTLV-III and has filed a patent on the method of production (14).

Conclusion

The involvement of multiple organizations in similar research activities that are addressed at different aspects of a common problem is arguably the best scenario for research. However, this scenario means that researchers are constantly striving to keep abreast of the work of others. In addressing the problem of AIDS, information has been shared through the informal networks that exist among PHS agencies and among their researchers. This sharing has been augmented by coordinating committees, external advisory committees, conferences, and cooperative agreements on funding extramural research and conducting intramural research.

Although most of these sharing and coordinating activities would have taken place regardless of any directive from PHS central management, there have been instances in which PHS (or departmental level) guidance could have led to better coordination. PHS might have directed NCI to share virus culture with CDC, and Secretary Heckler's announcement of the discovery of the etiologic agent for AIDS could have been more restrained.

Other possible impediments to the generation and dissemination of information are matters of more generalizable policy concerns that can only be raised in this memorandum. A systematic examination both of the methods by which the research grants and contracts process could be accelerated in public health emergencies and of the policy of keeping the research activities of commercial developers confidential may be needed.

HOW ADEQUATE ARE PHS'S RESOURCES DEVOTED TO AIDS PREVENTION AND TREATMENT?

As evidenced by the preceding discussions, PHS has accomplished a great deal with respect to AIDS: PHS grantees "discovered" AIDS as a syndrome; PHS has conducted surveillance of AIDS; and PHS investigators and others have made significant scientific advances, including the discovery of the probable etiologic agent for AIDS. PHS is currently coordinating development of a blood test for HTLV-III antibody; and research on treatment, vaccine development, and the many remaining questions about the natural history of the disease is progressing. It has not always been clear, however, that the amount of support for AIDS activities has been equivalent to the needs identified by PHS agencies (see, e.g., 146). Thus, OTA was asked to address whether PHS has devoted sufficient resources to its AIDS activities.

Resources for AIDS can be examined at two levels: 1) specific funding for AIDS activities, and 2) overall funding for specific PHS agencies. Although funding for AIDS research has been substantial, particularly in fiscal years 1984 and 1985, the history of specific funding for AIDS has been marked by continuing tension among the individual PHS agencies, DHHS, and Congress. Individual PHS agencies have consistently asked DHHS to request particular sums from Congress; the Department has consistently submitted requests for amounts smaller than those suggested by the agencies; and Congress typically has appropriated amounts greater than those requested by the Department. Except when prodded by Congress, DHHS has maintained that PHS agencies should be able to conduct AIDS research without extra funds, by obtaining money from their other activities. However, cutbacks and threatened cuts in overall funding and personnel levels have restricted the ability of affected agencies to redirect resources. The Administration has not pursued the option of seeking an appropriation for the Public Health Emergency Act, which established a revolving fund to be used for urgent government response to public health emergencies (Public Law 98-49; see 146).

In large part, PHS agencies' responses to the AIDS crisis have been facilitated by the transfer of money and personnel from other activities. By DHHS directive, the response to AIDS has concentrated on research into the biology of AIDS. Psychological and social factors related to AIDS, the service needs of AIDS patients, and public education and prevention have not been considered funding priorities.

The U.S. budget process has effects on PHS agencies apart from the amount of resources they can devote to AIDS activities. PHS agencies have been unable to plan their activities adequately because they have not known how much funding and staff will be available to them. Furthermore, the uneven distribution of resources has intensified competition among agencies, particularly now that an etiologic agent for AIDS has been discovered and there are many directions for research to take concurrently (e.g., treatment, vaccine development, cofactor research, natural history studies) and several areas in which agencies have overlapping expertise. The distribution of resources to activities not directly involving the etiologic agent remains an issue. Of particular importance is the question of whether sufficient resources are being devoted to the investigation of factors affecting the transmissibility of AIDS, treatment, public education, and prevention.

Five issues concerning the allocation of funds for AIDS to PHS remain open:

- the extent to which progress in other disease areas has suffered as a result of diversions to AIDS activities;
- the wisdom of limiting the priority status of AIDS primarily to biomedical research;
- the manner in which limited resources can be allocated among agencies;
- the particular problem of personnel ceilings; and
- the extent to which agencies will be able to pursue AIDS work adequately in the face of further cutbacks.

Specific Funding for AIDS Activities

As shown in table 1, Congress has consistently earmarked funds for AIDS activities at a level higher than that requested by the Administration, although not necessarily at levels requested by in-

Table 1.—History of AIDS Funding, Fiscal Years 1982 to 1985 (thousands of dollars)

	PHS agencies' request	President's budget request	Earmarked in congressional appropriations and/or actually obligated
Fiscal year 1985:			
President's budget request	$55,242[a]	$60,589[b]	$87,356[c]
Proposed budget amendment	35,809[a]	—[d]	
Estimated funds redistributed	—	—	10,070
Total	$91,051	$60,589	$97,426[b] [e]
Fiscal year 1984:			
President's budget request	$39,827[f]	$39,827[g]	$48,345
Supplement to original appropriation	20,076[a]	0	9,475[h]
Estimated funds redistributed[c]	—	—	3,640
Total	$59,903	$39,827	$61,460[i] [j]
Fiscal year 1983:			
President's budget request	0[f]	0[k]	—
Supplement to original appropriation	N.A.[l]	—	$2,000
Estimated funds redistributed[c]	—	—	26,736
Total	N.A.	—	$28,736[j] [m]
Fiscal year 1982:			
President's budget request	0[f]	0[n]	—
Supplement to original appropriation	0[f]	0[n]	500
Estimated funds redistributed[c]	—	—	5,055
Total	0	0[n]	$ 5,555[j] [m]

Notes:

[a] Source: E. N. Brandt, Jr., Assistant Secretary for Health, Public Health Service, U.S. Department of Health and Human Services, "Proposed FY 1984 and FY 1985 Amendment for Acquired Immunodeficiency Syndrome," memorandum to the Secretary of Health and Human Services, May 25, 1984.

[b] Source: E. N. Brandt, Jr., Assistant Secretary for Health, Public Health Service, U.S. Department of Health and Human Services, Washington, DC, letter to Office of Technology Assessment, U.S. Congress, Dec. 20, 1984.

[c] By subtraction.

[d] To be determined. In hearings before the House Energy and Commerce Subcommittee on Health on Sept. 17, 1984, the Assistant Secretary for Management and Budget testified that fiscal year 1985 supplemental AIDS funding would be addressed in connection with the submission of the 1986 budget in February 1985.

[e] Includes $8,350,000 for FDA which cannot be obligated until requested by the President.

[f] Actual figure not known, but assumed to be the same as the President's budget request.

[g] Source: U.S. Congress, House Committee on Government Operations, *The Federal Response to AIDS* (Washington, DC: U.S. Government Printing Office, 1983).

[h] Source: U.S. Congress, House of Representatives, "Making Supplemental Appropriations for the Fiscal Year Ending September 30, 1984, and for Other Purposes, Conference Report 98-977 (to accompany H.R. 6040), Aug. 10, 1984.

[i] Source: W. H. Little, Office of the Assistant Secretary for Health, Public Health Service, U.S. Department of Health and Human Services, Rockville, MD, personal communication, Dec. 28, 1984.

[j] Amount represents actual obligations, including funds redirected from other activities.

[k] No request for funds specifically for AIDS was made until May 1983 (U.S. Congress, House Committee on Government Operations, *The Federal Response to AIDS* (Washington, DC: U.S. Government Printing Office, 1983)). As of April 1983, PHS planned to spend $14.5 million on AIDS from existing allocations (U.S. Congress, House Committee on Government Operations, *The Federal Response to AIDS* (Washington, DC: U.S. Government Printing Office, 1983)).

[l] N.A. = Not available. CDC, but not NIH, identified funds needed. DHHS did not request them. Congress appropriated an additional $2 million for CDC's AIDS research in December 1982 (U.S. Congress, House Committee on Government Operations, *The Federal Response to AIDS* (Washington, DC: U.S. Government Printing Office, 1983).

[m] Source: W. H. Little, Office of the Assistant Secretary for Health, Public Health Service, U.S. Department of Health and Human Services, Washington, DC, personal communication, Oct. 26, 1984.

[n] No request for funds specifically for AIDS was made until May 1983.

dividual agencies. The Administration has maintained that AIDS activities can be funded from overall agency funds supplemented by appropriations initiated by Congress (see, e.g., 70). The Administration has continued to maintain this despite the fact that the special panel for AIDS resources established in the Office of the Assistant Secretary for Health (OASH) investigated and approved the amounts requested by individual agencies.

AIDS was not discovered until March 1981, so in fiscal year 1981, there was, of course, no opportunity for the Administration to request money for AIDS work in its initial budget requests. However, although the need for additional resources was becoming clear in late 1981 and 1982, no requests for funds were made in those years, not even through requests for transfer authorities. In August 1982, Congress appropriated additional funds for AIDS research in fiscal year 1982, primarily for CDC. Again in December 1982, Congress appropriated an additional $2 million for fiscal year 1983 CDC AIDS research, based on material prepared by CDC but not officially presented to Congress (146). The Administration did not acknowledge the need for funds specifically for AIDS until May 1983, when the Assistant Secretary for Health requested the authority to transfer funds across agency lines (19).

More recently, AIDS activities have been considered in the President's budgets, although at lesser amounts than those considered necessary by affected agencies. The Administration's initial budget request for fiscal year 1984 AIDS activities was for $14,461,000, compared to then estimated fiscal year 1983 expenditures of $14,132,000 (145). By August 1983, the expected spending level for fiscal year 1983 had risen to $25 million, but the Administration's official request for AIDS research and surveillance for fiscal year 1984 rose from $14.46 million to $17.7 million, $7.3 million less than expected fiscal year 1983 spending levels (146). Subsequent to congressional hearings, the Administration's request for fiscal year 1984 more than doubled, to $39.8 million (145). In contrast, Congress earmarked $48,345,000 for fiscal year 1984 AIDS research (150). It is not known what the desires of the affected agencies were at that point, but at least $3,045,000 was redirected from other areas to meet the needs of AIDS activities, as shown in table 2.

When the discovery of the agent for AIDS was announced in April 1984, the Assistant Secretary for Health asked PHS agencies to reevaluate the needs of their AIDS activities, for both fiscal years 1984 and 1985. On the basis of the agencies' reevaluations, which were assessed for reasonableness by the newly formed PHS AIDS Resources Panel, Assistant Secretary Brandt forwarded a memo to Secretary Heckler requesting a total supplemental appropriation of $20,076,000 and 4 full-time equivalents (FTEs) for fiscal year 1984 and a budget amendment of $35,809,000 and 37 FTEs for fiscal year 1985 (20).

The Assistant Secretary's requests were not forwarded to Congress by the Department, although several Members of Congress received copies of Assistant Secretary Brandt's memo. Instead, DHHS Secretary Heckler directed Assistant Secretary Brandt to use "resources currently available to the Public Health Service" and to review the funding status of AIDS after the passage of the second supplemental appropriations bill for 1984 and the regular appropriations bill for 1985 (70). The Secretary noted that PHS had been able to increase spending for AIDS by about $2.5 million over the funding levels in the fiscal year 1984 DHHS appropriations act, implying that funds were available in the agencies.

Despite the Department's inaction, Congress passed a supplemental appropriations bill in 1984 that included $9,475,000 for AIDS research. This was about half the amount initially requested by the affected PHS agencies (see table 3).

The President's initial budget request for AIDS for fiscal year 1985 was $55,242,000 (150). No changes were made in allocations to the various PHS agencies as a result of the discovery of the etiologic AIDS agent. (As discussed below, funds were redirected within agencies as a result of the discovery of the AIDS agent.) Table 4 compares the President's budget request for PHS agencies' AIDS activities for fiscal year 1985 and the amounts suggested by Congress in its final appropriation (Public Laws 99-473 [Continuing Resolution] and 98-619 [Appropriations]).

Table 2.—PHS Agencies' Estimated Obligations for AIDS Activities in Fiscal Year 1984

Agency	(1) Estimated obligations[a]	(2) PHS estimate of funds redirected[b] (included in column 1)
Centers for Disease Control (CDC)	$13,750	—
Food and Drug Administration (FDA)	798	$ 398
National Institutes of Health (NIH):		
National Cancer Institute (NCI)	16,627	2,150
National Heart, Lung, and Blood Institute (NHLBI)	4,871	154
National Institute of Dental Research (NIDR)	81	—
National Institute of Neurological and Communicative Disorders and Stroke (NINCDS)	1,510	145
National Institute of Allergy and Infectious Diseases (NIAID)	19,616	198
National Eye Institute (NEI)	60	—
Division of Research Resources (DRR)	1,356	—
Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA)	2,791	—
Health Resources and Services Administration (HRSA)	—	—
PHS total	$61,460	$3,045

Notes:

[a] Includes supplemental appropriations and $3,045 million redirected; Source: E. N. Brandt, Jr., Assistant Secretary for Health, Public Health Service, U.S. Department of Health and Human Services, Washington, DC, letter to Office of Technology Assessment, U.S. Congress, Dec. 20, 1984.

[b] Source: M. Gonzales, Public Health Service, U.S. Department of Health and Human Services, Washington, DC, personal communication, Nov. 8, 1984. Figures are approximate, and based on the difference between AIDS obligations at two points in time, one earlier (approximately July 1984) and one later (approximately August 1984). The assumption made by PHS was that any increases in obligations between the two points in time would have had to represent a redirection of funds initially obligated to other activities into AIDS activities (W. H. Little, personal communication, Dec. 28, 1984). Further estimates of the amounts redirected to AIDS from other activities in fiscal year 1984 have not been calculated by PHS.

Table 3.— Supplemental Funds for PHS Agencies' AIDS Activities in Fiscal Year 1984: Agencies' Indications Compared to Congressional Appropriations[a]

(thousands of dollars)

Agency	Agency indication[b]	Administration's request	Congressional appropriation[c]
CDC	$ 3,200	$—	$1,750
FDA	2,600	—	—
NIH:			
NCI	3,900	—	2,000
NIAID	8,330	—	4,150
NIDR	81	—	—
DRR	790	—	400
ADAMHA:			
NIMH[d]	375	—	375
NIDA[e]	800	—	800
HRSA	—	—	—
Total	$20,076	$—	$9,475

Notes:

[a] Initial agency indications were not forwarded to Congress by the Department of Health and Human Services.

[b] Source: E. N. Brandt, Jr., Assistant Secretary for Health, Public Health Service, U.S. Department of Health and Human Services, "Proposed FY 1984 Supplemental and FY 1985 Amendment for Acquired Immunodeficiency Syndrome," memorandum to the Secretary of Health and Human Services, May 25, 1984.

[c] Source: U.S. Congress, House of Representatives, "Making Supplemental Appropriations for the Fiscal Year Ending September 30, 1984, and for Other Purposes," Conference Report 98-977 (to accompany H.R. 6040), Aug. 10, 1984.

[d] NIMH = National Institute of Mental Health.

[e] NIDA = National Institute on Drug Abuse.

Table 4.—Amounts Identified for PHS Agencies' AIDS Activities for Fiscal Year 1985: President's Budget Request Compared to Congressional Appropriations or Estimated Actual Obligations

(thousands of dollars)

	Amounts identified for AIDS activities				
		Congressional appropriations			
Agency	(1) President's budget[a]	(2) Total[b c] (3)+(4)+(5)	(3) Conference levels before Cranston Amendment and redistribution	(4) Cranston Amendment[b d]	(5) Estimated redistribution needed[d]
CDC	$12,020	$23,200[e]	$12,000	$11,200	—
FDA	475	8,825[f]	8,825	—	—
NIH:					
DRR	779	1,731	1,731	—	—
NCI	18,951	26,851	21,351	—	$ 5,500[g]
NEI	61	300	300	—	—
NHLBI	8,459	8,884	8,884	—	—
NIAID	16,228	23,262	17,389	1,303[h]	4,570[h]
NIDR	35	411	411	—	—
NINCDS	1,150	1,150	1,150	—	—
ADAMHA	2,431	2,812	1,990	822	—
HRSA	—	—	—	—	—
PHS total	$60,589[i]	$97,426[h]	$74,031	$13,325	$10,070

Notes:

[a] Source: E. N. Brandt, Jr., Assistant Secretary for Health, Public Health Service U.S. Department of Health and Human Services, Washington, DC, letter to Office of Technology Assessment, U.S. Congress, Dec. 20, 1984.

[b] Sources: W. H. Little, Office of the Assistant Secretary for Health, Public Health Services, U.S. Department of Health and Human Services, Washington, DC, personal communication, Oct. 26, 1984; and E. N. Brandt, Jr., Assistant Secretary for Health, Public Health Service, U.S. Department of Health and Human Services, letter to Office of Technology Assessment, U.S. Congress, Dec. 20, 1984.

[c] Includes Cranston Amendment and estimated redistribution needed.

[d] Included in total congressional appropriations.

[e] Includes $4.5 million for addition to CDC virology building.

[f] Contingent on President's request for $8,350,000.

[g] Source: P. Fischinger, Associate Director, National Cancer Institute, National Institutes of Health, Bethesda, MD, personal communication, Nov. 6, 1984.

[h] Source: Y. duBuy, Financial Management Section, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD, personal communication, Nov. 6, 1984.

[i] Includes an increase of $5,347,000 over previous estimates for AIDS.

PHS agencies' needs for funds for AIDS activities in fiscal year 1985 have necessitated some redistribution of funds from other activities. At NIAID, between $5 million and $5.5 million has been identified as having to come from other activities, and at NCI, the figure is $4,570,000. CDC has said that it will not need to identify additional funds from other activity areas (119). Depending on the number of antibody-positive blood donors identified in its multicenter study of blood donors, NHLBI may have to request or identify additional funds from other activities (175).

In ADAMHA's opinion, all of the AIDS funds appropriated as part of the regular budget process have come from the agency's other activities. In other words, ADAMHA would have received the same total dollar amount for its budget regardless of how the funds were designated to be spent. Only supplemental appropriations and funds from the Cranston Amendment to the fiscal year 1985 appropriations for AIDS constituted additional money for AIDS activities (139).

No additional funds have ever been requested for the AIDS activities at HRSA, although the agency has been expected to participate in the PHS response to AIDS. HRSA's Division of Maternal and Child Health provides information on AIDS to recipients of the Maternal and Child Health Block Grant (which the Administration proposed transferring to OASH in DHHS (168)) and to Hemophilia Treatment Centers, which are funded through the Division of Maternal and Child Health, and recently helped organize a conference on pediatric AIDS. HRSA expects to be required to take a greater role in the AIDS situation as the number of pediatrics AIDS cases increases. An increased role for HRSA might require additional funds for the agency, and HRSA is optimistic that money could be obtained if the case were made to PHS. To date, HRSA has been told that the

PHS priority for AIDS refers to research into the biomedical aspects of AIDS, and PHS maintains that HRSA has had sufficient funding to complete the AIDS tasks assigned to it (22).

Funding for the PHS Agencies as a Whole

DHHS has encouraged PHS agencies involved in AIDS research to take money and personnel from other activities to avoid asking Congress for additional funds. However, cutbacks and threatened cutbacks in funding and, in particular, in personnel levels have restricted the ability of affected agencies to redirect resources to AIDS-related activities. Tables 5, 7, 9, 10, and 12 compare funding levels suggested in the President's budgets for the years 1983, 1984, and 1985 for CDC, FDA, NIH, ADAMHA, and HRSA, respectively. Tables 6, 8, and 11 show actual overall agency and AIDS budgets for CDC, FDA, and ADAMHA.

Table 5.—Centers for Disease Control: Initial U.S. Budget Request Compared to Estimated Budget Authority for Previous Year, Fiscal Years 1983 to 1985[a] (thousands of dollars)

	1985R[b]	1984E[c]	1984R	1983E	1983R	1982E
CDC budget:						
Excluding preventive health block grant[d]	$280,364	$286,310	$270,023	$243,372	$217,192	$202,010
Including preventive health block grant[d]	$369,864	$374,504	$356,352	$329,701	$298,792	$283,610
Percentage increase or decrease over previous year:						
Excluding block grant	−2.1%	—	10.9%	—	7.5%	—
Including block grant	−1.2%	—	8.1%	—	5.4%	—
CDC FTEs[e]	3,923	4,178	3,975	4,058	3,983	4,268
Infectious diseases budget:[f]	$ 46,161	$ 49,885	34,417	$ 34,882	N.A.[g]	N.A.
Percentage increase or decrease over previous year	−7.5%	—	−1.3%	—	—	—

Notes:

[a] Source: Budget of the U.S. Government, Fiscal Years 1963 to 1985.

[b] R = Budget request.

[c] E = Estimated budget authority.

[d] The President's budget proposed that preventive health block grant funds be transferred from CDC to the Office of the Assistant Secretary for Health (OASH). CDC budgets both including and excluding the preventive health block grant are shown here because excluding administration of the block grant would affect CDC's size and activity. The preventive health block grant was not transferred to OASH in either fiscal year 1984 or 1985.

[e] FTEs = Full-time equivalents.

[f] The CDC AIDS Activity is located in the CDC Center for Infectious Diseases.

[g] N.A. = Not available.

Table 6.—Centers for Disease Control: Overall Agency Budgets and AIDS Budgets, Fiscal Years 1979 to 1985[a] (thousands of dollars)

	1985	1984	1983	1982	1981	1980	1979
Overall CDC budget:	$410,530	$380,489	$353,476	$302,242	$288,228	$296,125	$263,972
Precentage increase or decrease over previous year	7.9%	7.6%	17.0%	4.9%	−2.7%	12.2%	—
CDC FTEs[b]	4,401[c]	4,198	4,070	4,317	4,245[c]	4,052[c]	4,048
AIDS budget:							
Budget	$ 23,200[d]	$ 13,750[e]	$ 4,225[f]	$ 500[g]	$ 200	—	—
Plus funds redirected from other activities	—	—	$ 1,977[h]	$ 1,550[h]	—	—	—
Total	$ 23,200	$ 13,750	$ 6,202	$ 2,050	$ 200	—	—
FTEs	155[c i]	80[c]	45	—	—	—	—

Notes:

[a] Source: Except where otherwise noted, B. Shepard, Centers for Disease Control, Atlanta, GA, personal communication, Oct. 16, 1984.

[b] FTEs = Full-time equivalents.

[c] Source: E. N. Brandt, Jr., Assistant Secretary for Health, Public Health Service, U.S. Department of Health and Human Services, Washington, DC, letter to Office of Technology Assessment, U.S. Congress, Dec. 20, 1984.

[d] Includes $4,500,000 for CDC virology building.

[e] Includes $1,750,000 in supplemental appropriations.

[f] Includes $2,225,000 in supplemental appropriations.

[g] Supplemental appropriation.

[h] Redirected from surveillance of hepatitis, studies of chlamydial infections and pelvic inflammatory diseases, purchases of laboratory supplies and equipment, studies of influenza risk factors and vaccines.

[i] Estimated.

Table 7.—Food and Drug Administration: Initial U.S. Budget Request Compared to Estimated Budget Authority for Previous Year, Fiscal Years 1983 to 1985[a] (thousands of dollars)

	1985R[b]	1984E[c]	1984R	1983E	1983R	1982E
FDA budget	$394,004	$382,574	$385,933	$349,130	$356,163	$328,032
Percentage increase over previous year	3%	—	10.5%	—	8.6%	—
FDA FTEs[d]	7,094	7,191	7,163	7,164	7,180	7,192

Notes:

[a] Source: Budgets of the U.S. Government, Fiscal Years 1983 to 1985.

[b] R = Budget request.

[c] E = Estimated budget authority.

[d] FTEs = Full-time equivalents.

Table 8.—Food and Drug Administration: Overall Agency Budgets and AIDS Budgets, Fiscal Years 1979 to 1985[a] (thousands of dollars)

	1985	1984	1983	1982	1981	1980	1979
Overall FDA budget	$409,700[b]	$394,817	$361,645	$338,268	$327,927	$320,852	$295,154
Percentage increase over previous year	3.8%	9.2%	6.9%	3.2%	2.2%	8.7%	—
FDA FTEs[c]	7,068[b]	7,090	7,090	7,159	7,777	7,623[d]	7,561[d]
AIDS budget	$ 8,825[b]	$ 798	$ 350	$ 150	—	—	—
FTEs	20[b]	8[e]	7[e]	—	—	—	—

Notes:

[a] Sources: J. Biviano, Budget Analyst, Food and Drug Administration, Rockville, MD, personal communication, Aug. 28, 1984; and C. L. Wilburn, Food and Drug Administration, Rockville, MD, personal communication, Nov. 5, 1984.

[b] Estimate based on continuing resolution. Twenty FTEs are in question and $8.3 million will have to be requested by the President in order to be obligated.

[c] FTEs = Full-time equivalents.

[d] Actual positions; accounting conversion had not been made to FTEs.

[e] Redirected from other activities (hepatitis, herpes, pertussis, cytomegalovirus, and chickenpox).

Table 9.—National Institutes of Health: Initial U.S. Budget Request Compared to Estimated Budget Authority for Previous Year, Fiscal Years 1983 to 1985[a] (thousands of dollars)

	1985R[b]	1984E	1984R	1983E	1983R	1982E
NCI budget	$1,101,069	$1,077,303	$989,263	$983,576	$955,449	$986,617
Percentage increase or decrease over previous year	2.2%		0.6%		−3.2%	
NCI FTEs[d]	2,292	2,387	2,259	2,289	2,370	2,504
NIAID budget	$ 325,379	$ 314,117	$281,405	$273,581	$246,043	$235,895
Percentage increase over previous year	3.6%		2.9%		4.3%	
NIAID FTEs	730	762	768	772	814	837
NHLBI budget	$ 718,852	$ 703,197	$628,028	$622,745	$577,143	$559,637
Percentage increase over previous year	2.2%		0.8%		3.1%	
DBDR[e]	$ 104,890	$ 102,466	$ 87,930	$ 87,572	$ 78,339	$ 77,563
NHLBI FTEs	913	954	888	900	934	936
NIDR budget	$ 91,096	$ 88,163	$ 80,583	$ 78,860	$ 74,462	$ 71,983
Percentage increase over previous year	3.3%		2.2%		3.4%	
NIDR FTEs	347	362	341	348	369	385
NINCDS budget	$ 344,601	$ 335,205	$301,022	$295,719	$274,505	$265,901
Percentage increase over previous year	2.8%		1.8%		3.2%	
NINCDS FTEs	705	735	720	730	733	763
NEI budget	$ 157,873	$ 154,683	$143,276	$141,561	$131,550	$127,374
Percentage increase over previous year	2.1%		1.2%		3.3%	
NEI FTEs	205	213	224	218	222	227
DRR budget	$ 245,728	$ 242,636	$228,542	$213,804	$191,024	$184,177
Percentage increase over previous year	1.3%		6.9%		3.7%	
DRR FTEs	96	100	98	99	99	96

Notes:

[a] Source: Budgets of the U.S. Government, Fiscal Years 1983 to 1985.

[b] R = Budget request.

[c] E = Estimated budget authority.

[d] FTEs = Full-time equivalents.

[e] DBDR = Division of Blood Diseases and Resources.

Table 10.—Alcohol, Drug Abuse, and Mental Health Administration: Initial U.S. Budget Request Compared to Estimated Budget Authority for Previous Year, Fiscal Years 1983 to 1985[a] (thousands of dollars)

	1985R[b]	1984E[c]	1984R	1983E	1983R	1982E
ADAMHA budget:						
Including service block grant[d]	$844,955	$846,206	$792,854	$777,556	$737,177	$751,007
Excluding service block grant[d]	$372.655	$384,206	$357,826	$338,556	$305,177	$322,912
Percentage increase or decrease over previous year:						
Including service block grant	−0.1%	—	2.0%	—	−1.8%	—
Excluding service block grant	−3.0%	—	5.7%	—	−5.5%	—
ADAMHA FTEs[e]	1,608	1,707	1,698	1,758	1,694	1,757
NIMH[f] budget	$226,318	$250,547	$220,348	$225,985	$195,783	$224,553
Percentage increase or decrease over previous year	−9.7%	—	−2.5%	—	−12.8%	—
NIDA[g] budget	$ 79,270	$ 70,301	$ 71,689	$ 61,202	$ 60,334	$ 57,846
Percentage increase or decrease over previous year	12.8%	—	17.1%	—	4.3%	—

Notes:

[a] Source: Budgets of the U.S. Government, Fiscal Years 1983 to 1985.

[b] R = Budget request.

[c] E = Estimated budget authority.

[d] The budget proposed transfer of service block grant to the Office of the Assistant Secretary for Health, but the transfers were not approved by Congress.

[e] FTEs = Full-time equivalents.

[f] NIMH = National Institute of Mental Health.

[g] NIDA = National Institute on Drug Abuse.

Table 11.—Alcohol, Drug Abuse, and Mental Health Administration: Overall Agency Budgets and AIDS Budgets, Fiscal Years 1982 to 1985[a] (thousands of dollars)

	1985	1984	1983	1982
Overall ADAMHA budget	$434,093	$384,411	$340,866	$332,423
(NIMH)	(283,626)	(251,035)	(227,342)	(229,319)
(NIDA)	(81,410)	(71,098)	(61,854)	(56,564)
Percentage increase or decrease over previous year:	12.9%	12.8%	2.5%	—
(NIMH)	(12.9%)	(10.4%)	(−0.9%)	—
(NIDA)	(14.5%)	(14.9%)	(9.3%)	—
ADAMHA FTEs[b]	N.A.[c]	1,659	1,660	1,624
AIDS budget	$ 2,812	$ 2,791	$ 516	—
(NIMH)	(1,787)	(1,205)	(202)	—
(NIDA)	(1,025)	(1,586)	(314)	—

Notes:

[a] Sources: E. N. Brandt, Jr., Assistant Secretary for Health, Public Health Service, U.S. Department of Health and Human Services, Washington, DC, letter to Office of Technology Assessment, U.S. Congress, Dec. 20, 1984; and U.S. Department of Health and Human Services, Public Health Service, Alcohol, Drug Abuse, and Mental Health Administration, "ADAMHA AIDS Research," xerox copy dated Dec. 14, 1984.

[b] FTEs = Full-time equivalents.

[c] N.A. = Not available.

Table 12.—Health Resources and Services Administration: Initial U.S. Budget Request Compared to Estimated Budget Authority for Previous Year, Fiscal Years 1983 to 1985[a] (thousands of dollars)

	1985R[b]	1984E[c]	1984R	1983E	1983R	1982E
HRSA budget:						
Excluding block grants[d]	$ 245,419	$ 459,031	$ 292,444	$ 481,208	—	—
Including block grants[d]	$1,187,119	$1,380,151	$1,127,816	$1,315,226	$1,724,143	$1,401,922
Percentage increase or decrease over previous year:						
Excluding block grants	−46.5%	—	−39.2%	—	—	—
Including block grants	−14.0%	—	−14.2%	—	23.0%	—
HRSA FTEs[e]	2,704	3,746	3,731	4,627	3,787	4,874

Notes:

[a] Source: Budgets of the U.S. Government, Fiscal Years 1983 to 1985.

[b] R = Budget request.

[c] E = Estimated budget authority.

[d] The President's budgets for fiscal years 1984 and 1985 proposed that several block grants be transferred to the Office of the Assistant Secretary for Health (OASH). HRSA budgets both including and excluding the block grants are shown here because excluding administration of the grants would have affected HRSA's size and activity including AIDS activities. For example, the proposed transfers included the Maternal and Child Health Block Grant, the program through which HRSA informs grant recipients of information about AIDS. The block grants were not transferred to OASH in either fiscal year 1984 or 1985.

[e] FTEs = Full-time equivalents.

As shown in table 5, for fiscal year 1985, the President requested a reduction in overall funds and personnel ceilings for CDC relative to estimated budget authority for the previous year. A reduction in funding from previous levels for the CDC Infectious Diseases Activity, of which the AIDS Activity is a part, was also requested in both 1984 and 1985, when, as shown in table 6, CDC's actual AIDS expenditures have been increasing at a growing rate over the years. CDC was especially affected by budget cutbacks in the period when it was starting to become heavily involved in AIDS activities. As shown in table 6, the agency's overall budget was reduced by almost $8 million, or 2.7 percent, from 1980 to 1981. The 1982 appropriation brought CDC's budget back to approximately the 1980 level. In 1983, although the overall agency budget increased a substantial amount, the number of FTEs at CDC declined to 4,070 from 4,317.

Levels of funding have similarly varied over the years for other PHS agencies involved in AIDS activities. As shown in table 7, the President's budget suggested 8.6- and 10.5-percent increases in funding for FDA in fiscal years 1983 and 1984, but only a 3-percent increase in funding for fiscal year 1985. FDA is responsible for evaluating the blood test for AIDS and the safety and efficacy of blood products and vaccines.

As shown in table 9, presenting figures for NIH, the President's budget for 1983 suggested a 3.2-percent decrease in funding for NCI. Only minimal increases in funding were suggested for NCI and most of the other NIH institutes in fiscal years 1984 and 1985. If inflation is taken into account, these minimal increases would represent decreases in funding. (A 14-percent increase in funding for the seven NIH institutes involved in AIDS activities was approved by Congress for fiscal year 1985: actual appropriations for the institutes involved were $1,183,806,000 for NCI; $370,965,000 for NIAID; $805,269,000 for NHLBI; $396,885,000 for NINCDS; $181,678,000 for NEI; $100,688,000 for NIDR; and $304,025,000 for DRR).

The Administration's pattern for ADAMHA overall, as shown in table 10, has been to suggest more decreases than increases, although increases in funding have been suggested for NIDA. As shown in table 11, appropriations for ADAMHA have increased since 1982. Except for fiscal year 1983, as shown in table 12, the Administration has also suggested substantial decreases in funding for HRSA. (HRSA's actual fiscal year 1985 appropriation was $1,427,694,000.)

Of greater impact than suggestions for holding funding levels about even or decreasing them have been budget requests by the Administration for decreases in PHS agencies' FTE personnel ceilings. The Administration has consistently suggested decreases in personnel ceilings for CDC, FDA, NCI, NIAID, NHLBI, NIDR, NINCDS, ADAMHA, and HRSA. Small increases were suggested for NEI in the 1984 budget and for DRR in the 1983 budget. Decreases in personnel have actually occurred at several of the agencies at critical times. No additional personnel resources have been allocated to NIAID for any of its AIDS activities (etiology, natural history, immunology, treatment, and prevention research) (166).

How AIDS and Other Activities Have Been and Will Probably Be Affected by Funding Patterns

The effect of funding patterns for AIDS has varied over time and by agency. Initially, the lack of resources impeded the funding of extramural research (NCI and NIAID), prospective studies of high-risk individuals (NIH and CDC), and animal studies (CDC) (146). As the Nation's public health monitor, CDC is required to conduct surveillance of a number of diseases and public health outbreaks. FDA's mission is to develop criteria to help it evaluate the safety and efficacy of the products it regulates. Thus, neither agency was easily able to redirect funds and staff into the area of AIDS without sacrificing other important work. The mission of NIH agencies is basic research, much of which may be advanced by involvement in the AIDS problem. Thus, in NIH laboratories, redirections of staff to work on AIDS have not detracted from other activities as much as have redirections of staff at CDC and FDA. This situation at NIH, especially for NCI and NIAID, may change in 1985.

In 1981, 1982, and 1983, CDC redirected funds and personnel from a number of activities (e.g., surveillance of hepatitis, studies of chlamydial infections and pelvic inflammatory diseases, studies of influenza risk factors and vaccines, and purchases of laboratory supplies and equipment) to support AIDS activities. In more recent fiscal years, including fiscal year 1985, Congress has appropriated amounts greater than those initially requested by the Administration for AIDS, so the redistribution of CDC funds from other activities has not been necessary (119). Personnel ceilings at CDC remain a problem. Three or four additional staff are needed for a study of blood recipients, but they cannot be promised until the fiscal year 1985 budget is settled. Congress has recommended a personnel "floor" of 4,400 for CDC. In the appropriations, 155 FTEs were specified for AIDS. As of November 1984, only 80 had been received, and CDC will not find out about the remainder until OMB completes its budget process (119). CDC's coordinator of AIDS activities was not optimistic about getting additional FTEs (38). The way budgets have been processed has consistently impeded the making of plans at CDC (51).

FDA (see tables 7 and 8) has had largely the same problem as CDC. In the past, personnel and funds have been redirected from work on interleukin-2 for herpes, chicken pox, and other related viruses; improvement of current vaccines for pertussis; and research associated with hepatitis vaccines (177). Currently, even though it is well into fiscal year 1985, FDA's appropriation is under a continuing resolution. Additional problems are caused by the facts that $8.3 million of the money designated for AIDS by Congress must be requested by the President before it is obligated; and a reduction in overall agency FTEs was recommended by the Administration and approved by Congress.

As noted, NIAID and NCI historically have had fewer problems with the redistribution of funds from other activities than have CDC and FDA. In addition, because they are part of a larger agency, NCI and NIAID have been able jointly to fund extramural research projects and lend each other laboratory and other personnel. Currently, NIAID continues to have problems obtaining staff to conduct statistical analyses for its five-city study of high-risk gay men, and NIAID did not receive a fiscal year 1985 appropriation adequate to meet the needs it articulated in the Assistant Secretary for Health's memo to the Secretary of DHHS requesting a budget amendment.

NIAID plans to spend $23,262,000 in fiscal year 1985 on its AIDS activities, $4,570,000 of which will be redirected from other activities (see tables 4 and 13). This redistribution was necessary to fund continuation costs of activities supported as a result of the fiscal year 1984 supplemental appropriation of $4,150,000. As shown in table 13, the redistribution of funds from other activities means that new grants covering the gamut of NIAID activities will not be funded; certain non-AIDS projects that had been planned will not be started. In addition, certain new AIDS projects that had been requested will be foregone or postponed (142). These include the following (41):

Table 13.—National Institute of Allergy and Infectious Diseases: Redistribution Needed To Fund Fiscal Year 1985 AIDS Activities[a] (thousands of dollars)

	Amount	Source
	$2,258	18 competing research project grants (covering the gamut of infectious diseases and immunology) will not be funded
	$1,542	Congressionally requested major new clinical trials on: • ribavirin therapy of viral respiratory diseases • candidate vaccines for Group B streptococcal infections
	$ 770	Intramural research on vaccine development other than for AIDS: • hepatitis • rotavirus diarrhea • pertussis
Total	$4,570	

Note:
[a] Source: Y. duBuy, Financial Management Section, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD, personal communication, Nov. 6, 1984.

- extramural studies of the development of new vaccines and antiviral drugs for HTLV-III infection;
- extramural studies to develop animal model systems for testing vaccines and antiviral drugs for HTLV-III infection;

- intramural clinical protocols of treatment regimens directed at HTLV-III virus as well as immune defects resulting from viral infections;
- investigations of immune derangements in addicted parents and children;
- epidemiological cohort study of HTLV-III infections in health care workers; and
- support for additional AIDS outreach programs directed at health care workers.

NCI will also have to change its funding patterns in fiscal year 1985, and anticipates some problems as a consequence of changes in personnel ceilings. NCI did not receive any funds under the Cranston Amendment (see table 4), to the chagrin of two of its Boards of Scientific Counselors (Boards of the Division of Cancer Etiology and the Division of Cancer Treatment) (163,176). In order to fund AIDS activities in 1985, NCI will take funds from its research projects grants center, cancer centers, cooperative clinical research, career program development, and clinical education (see table 14). NCI also foresees significant problems at the end of the current contract year when it will be unable to fund continuing costs for anticipated subcontracts at the Frederick (Maryland) Cancer Facility begun with funding from the fiscal year 1984 supplemental appropriation. The subcontracts will be a key element in vaccine development research and it is unlikely that the research can be completed in 1 year (162).

Table 14.—National Cancer Institute: Estimated Redistribution Needed To Fund Fiscal Year 1985 AIDS Activities[a] (thousands of dollars)

	Amount	Source
	$2,550 to $2,800	Research project grants pool
	850 to 930	Cancer centers
	850 to 930	Cooperative clinical research
	550 to 610	Career program development
	200 to 230	Clinical education
Total	$5,000 to $5,500	

Note:
[a] Sources: P. Fischinger, Associate Director, National Cancer Institute, National Institutes of Health, Bethesda, MD, personal communications, Nov. 6, 1984, and Jan. 3, 1985; and E. N. Brandt, Jr., Assistant Secretary for Health, Public Health Service, U.S. Department of Health and Human Services, Washington, DC, letter of Office of Technology Assessment, U.S. Congress, Dec. 20, 1984.

In addition to funding problems, a number of factors have come together to make NCI vulnerable to personnel cutbacks. Prior to a year and a half ago, a category of personnel called "special experts" could be hired without being counted against NIH's personnel ceilings. When the policy was first changed and the experts began to be counted against the NIH personnel ceiling, it did not have much impact on NCI, because most of the institutes at NIH were under ceiling, so the NIH in the aggregate was within the agency limitation. Personnel slots can be "loaned" across agencies at NIH. Now, however, the other institutes are up to strength and are subject to an NIH hiring freeze which sets positions at 13,507 FTEs. NIAID had loaned NCI nine positions and now needs them back. As a consequence, NCI is currently under a restriction to hire only one person for every two who leave the institute (162). NIAID foresees that it may have the same restriction (166). According to OASH, however, NIAID will be able to hire three persons for every five who leave, the restrictions on NCI are in effect only until NIH receives its final ceiling for 1985, and the NIH Director has discretion to grant exceptions to the restriction for high-priority needs (22). These changes reduce the prospects of hiring appropriate personnel for specific project initiatives in 1985. Thus, for example, NIH expects to have to make cutbacks in its Clinical Center nursing staff, which means that fewer patients will be available for clinical trials and treatment.

Measures To Increase the Number of Extramural Research Projects

One of the early criticisms of NIH was its inattention to extramural research on AIDS. Critics charged that not enough extramural research was being funded and that what was being funded was taking an unconscionably long time to go through the system. In order to deal with the problem of long delays in funding, NIH initiated mail ballots and other procedures to expedite extramural grant reviews. Subsequently, the award rate at the three NIH institutes most heavily involved in AIDS activities (NCI, NHLBI, and NIAID) was greatly accelerated. For 1983, as shown in table 15, the award rate, or the number of approved grants actually funded, in all areas at all three institutes was around 35 percent; for AIDS, the award rates were 67 percent for NCI, 100 percent for NHLBI,

Table 15.—National Institutes of Health Award Rates and Paylines for All Extramural Research Compared to AIDS Extramural Research, Fiscal Year 1983[a]

	NCI	NHLBI	NIAID
All extramural research:			
Number of grants approved for funding	2,610	2,114	1,406
Number of grants actually funded	886	748	522
Award rate	34%	35%	37%
Payline (priority score at which approximately 90% of grants were funded)	181	195	166
AIDS extramural research only:			
Number of grants approved for funding	45	2	17
Number of grants actually funded	30	2	17
Award rate	67%	100%	100%
Number of grants funded at priority score ranges:[b]			
100-180	8	—	12
181-200	5	1	2
201-250	7	—	2
251-300	10	1	1

Notes:

[a] Source: N. D. Mansfield, Division of Financial Management, National Institutes of Health, Bethesda, MD, letter to Office of Technology Assessment, U.S. Congress, Oct. 22, 1984.

[b] The lower the score, the higher the priority.

and 100 percent for NIAID For NCI, this meant that a number of extramural grants receiving rather poor priority score ranges were funded (the lower the score, the higher the priority for funding). ADAMHA also expedited its review process and funded projects beyond usual priority scores (151). However, while the use of lower standards for AIDS research by all of the agencies mentioned undoubtedly increased the number of grants funded, it is believed that it also resulted in the funding of some studies of poor quality (56).

Resources for Research on Cofactors and Treatment and for Public Education

In addition to the issue of whether sufficient resources are being allocated to AIDS activities by DHHS and Congress, there remains the question of how resources are being allocated to the various AIDS activities. In particular, doubts have been raised about the adequacy of resources devoted to the search for factors affecting the development of AIDS, the provision of treatment, and public education. In this section, the proportion of the AIDS budget directed at these activities is summarized.

Cofactor Research

In general, the search for factors affecting the development of AIDS has always accounted for a large proportion of the AIDS budget. Immediately after the discovery of the etiologic agent for AIDS, changes in resource allocations were made. As shown in table 16, which represents funding estimates for PHS AIDS activities as of September 11, 1984, for both fiscal years 1984 and 1985, greater amounts were budgeted for cofactor research and epidemiologic studies (items 1b and 4 in the table) after the discovery of HTLV-III than before it. As shown in table 17, which represents the most current estimates, PHS estimates that of the total PHS resources allocated to AIDS in fiscal year 1984, 12.6 percent was obligated to cofactor research, and 31.9 percent, to epidemiologic studies. In fiscal year 1985, a relatively greater proportion (14.9 percent) of total AIDS resources will be obligated to cofactor research, but a substantially smaller proportion (26 percent) will be obligated to epidemiologic studies. In total dollars, however, almost $5 million more will be obligated to epidemiologic studies in fiscal year 1985 than in 1984, and $6 million more to cofactor research.

It is more difficult to estimate the amounts being spent by PHS for research into psychosocial risk factors. As shown in table 17, research on psychosocial factors (item 8 in the table) constitutes a relatively small amount of total fiscal year 1985 resources for AIDS (2.1 percent of the budget, equal to $1,949,000). Furthermore, this category, as defined by PHS, includes research both on the psychosocial consequences of AIDS and on psychosocial factors which might contribute to its development. Possible psychosocial risk factors for AIDS include life stress, exhaustion, health habits, depression, anxiety, coping mechanisms, a sense of helplessness, and the loss of social support (see, e.g., 8,35,95,110).

Several studies of psychosocial risk factors and consequences of AIDS are being supported by NIMH (see app. D). The investigation of psychosocial factors has also been incorporated into epi-

Table 16.—Changes in Funding for PHS AIDS Activities Anticipated After Discovery of AIDS Etiologic Agent[a,b] (thousands of dollars)

Activity	Fiscal year 1984				Fiscal year 1985			
	Appropriation (Public Law 98-139) before discovery		Obligation respread after discovery[c]		President's budget			
					Before discovery		After discovery	
1. Etiologic agent and cofactors:								
a. Discovery	21%	$10,697	13%	$ 6,357	10%	$ 5,654	5%	$ 2,797
b. Confirmation and extension of observations on causative agent and discovery of role of coinfections and cofactors	6	2,949	8	4,010	1	689	6	3,337
2. Development and evaluation of blood tests:								
a. Development	6	2,949	5	2,309	5	2,932	3	1,553
b. Evaluation	1	559	4	1,895	5	3,109	6	3,175
3. Surveillance	6	3,100	6	3,092	6	3,260	6	3,260
4. Epidemiological studies (to determine natural history of AIDS)	27	13,756	32	16,279	38	21,231	40	22,651
5. Development of evaluation of vaccine (including animal model)	3	1,477	3	1,477	4	2,237	5	2,554
6. Studies of therapeutic intervention:								
a. AIDS	7	3,414	7	3,414	8	4,471	8	4,337
b. Opportunistic infections	10	5,183	10	5,212	9	5,149	9	5,247
7. Immunologic studies	6	3,023	6	3,023	6	3,238	6	3,238
8. Psychosocial factors	1	709	1	709	2	1,009	2	1,009
9. Simian AIDS	4	1,808	4	1,808	3	1,791	3	1,612
10. Prevention of transfusion-related AIDS	0	22	0	22	1	550	1	550
11. Bioethics and biosafety	0	168	0	207	0	260	0	260
12. Information dissemination/public affairs	2	964	2	964	2	973	2	973
PHS total	100%	$50,778	100%	$50,778	100%	$56,553	100%	$56,553

Notes:

[a] Figures are approximate and represent calculations before passage of the supplemental appropriation for fiscal year 1984 and the appropriation for fiscal year 1985.

[b] Source: U.S. Department of Health and Human Services, "AIDS Public Health Service Total," xerox copy provided by W. H. Little, Office of the Assistant Secretary for Health, sheets dated July 27, 1984, and Sept. 11, 1984.

[c] After the discovery of HTLV-III as the probable etiologic agent for AIDS, the remaining $29,106,000 available for obligations for various activities was redistributed or "respread" among the activities.

Table 17.—Funding for PHS AIDS Activities by Type of Activity, Fiscal Years 1984 and 1985[a] (thousands of dollars)

Activity	Fiscal year 1984 obligation as of 9/30/84		Fiscal year 1985 appropriation	
1. Etiologic agent and cofactors:				
a. Discovery	8.2%	$ 5,058	—	—
b. Confirmation and extension of observations on causative agent and discovery of role of coinfections and cofactors	12.6	7,732	14.9%	$13,804
2. Development & evaluation of blood tests:				
a. Development	1.7	1,070	1.9	1,754
b. Evaluation	1.7	1,066	4.9	4,569
3. Surveillance	4.5	2,772	4.7	4,400
4. Epidemiological studies (to determine natural history of AIDS)	31.9	19,600	26.0	24,119
5. Development and evaluation of vaccine (including animal model)	4.7	2,879	12.7	11,776
6. Studies of therapeutic intervention:				
a. AIDS	6.3	3,852	8.8	8,158
b. Opportunistic infections	8.1	4,957	6.0	5,554
7. Immunologic studies	11.0	6,753	10.1	9,444
8. Psychosocial factors	1.8	1,105	2.1	1,949
9. Simian AIDS	4.2	2,589	2.7	2,546
10. Prevention of transfusion-related AIDS	0.9	522	0.9	882
11. Bioethics and biosafety	0.1	82	0.2	144
12. Information dissemination/public affairs	2.3	1,423	4.1	3,827
PHS total	100%	$61,460	100%	$92,926[b]

Notes:

[a] Source: E. N. Brandt, Jr., Assistant Secretary for Health, Public Health Service, U.S. Department of Health and Human Services, Washington, DC, letter to Office of Technology Assessment, U.S. Congress, Dec. 20, 1984.

[b] Excluding $4.5 million for CDC virology lab.

emiologic studies being conducted under the aegis f other agencies. Thus, for example, NIAID's pro- pective study of 5,000 apparently healthy gay ıen in five cities has incorporated some psycho- ɔcial items (depression, life satisfaction, self- steem, social support, sense of control) into its asic questionnaire, and grantees are free to de- elop additional questions. However, most of the esearch on risk factors concentrates on factors ther than the psychosocial: cytomegalovirus, pstein-Barr virus, herpes virus, hepatitis, the trogenic effect of steroids and other medicines, lcohol and other recreational drug use, smok- ıg, sexual practices, ethnicity, and particular nderlying diseases (165).

As shown in table 18, all of the PHS agencies, xcept FDA and HRSA, are involved in the in- estigation of coinfections and cofactors (item 1b) nd in epidemiologic studies to determine the nat- ral history of AIDS (item 4). Further details on ıe proportion of resources being devoted to the arious AIDS activities by each agency, including ofactors and epidemiologic research, are pro- ided in appendixes C and D.

reatment

Tables 17 and 18, and appendix C, indicate the elative proportion of PHS resources being de- oted to research on treatment. As shown in table 7 (item 6), the most recent calculations indicate ıat 14.8 percent ($13,712,000) of the AIDS budg- : for fiscal year 1985 was to be used for studies f therapeutic intervention (8.8 percent for AIDS nd 6 percent for opportunistic infections). These ıclude studies of the drugs suramin, ribavirin, entamidine, and dapsone; the use of polyamine ıhibitors to control cytomegalovirus infections; nd the use of interferon and interleukin-2. They o not include the study of psychosocial factors elated to treatment, which are included in the 2.1 ercent of the budget allocated to psychosocial ıctors (item 2 in table 17). The PHS emphasis as been on studies of biological treatment. In ad- ition, except for the treatment given to AIDS pa- ents at the NIH Clinical Center and the benefits atients gain from certain PHS activities (e.g., ublic education efforts directed at health care vorkers, the funding of researchers in extramural hospitals), no PHS funds have been allocated to the treatment of AIDS patients per se. The NIH Clinical Center is a research hospital to which patients are admitted on the basis of ongoing protocols, not need for treatment. The role of Federal agencies other than PHS in obtaining money for treatment for individual patients is discussed in the "Related Issues" section below.

Public Education and Prevention

In the past, relatively little money was allocated to public education about AIDS. Between 1984 and 1985, however, the amount allocated for such activities in the PHS agencies more than doubled, from $1.4 million to $3.8 million, most of it for CDC (item 12 in tables 17 and 18).

The AIDS budget of the Office of Public Affairs in OASH, where much of the public education has taken place, is scheduled to decrease to $120,000 in fiscal year 1985, from $200,000 in fiscal year 1984. PHS's public education activities are discussed further in the "Related Issues" section below.

PHS View and OTA Conclusions

In general, PHS believes that OTA's review of resources for AIDS is overly critical, especially with respect to fiscal year 1985. In his response to the first draft of this report, Assistant Secretary for Health Brandt said that OTA failed to give adequate credit to PHS for the "massive effort" it has mounted in response to the AIDS problem. "Although it is true that each of the PHS agencies has had to make readjustments and reallocations of its resources," the Assistant Secretary wrote; "we have nevertheless been successful in mounting a coordinated attack in the fight against AIDS. I assure you that adequate funds have been appropriated for fiscal year 1985 to permit the PHS agencies to carry out all of the AIDS requirements which have been presented to me" (22). More specifically, PHS agencies whose comments were transmitted by the Assistant Secretary stated that other activities will not suffer from a reallocation of resources to AIDS activities in fiscal year 1985, that the fiscal year 1985 mix of AIDS activities is appropriate to meet require-

Table 18.—Funding for PHS AIDS Activities by Type of Activity and Agency, Fiscal Years 1984 and 1985[a] (thousands of dollars)

Activity	Fiscal year 1984 obligation as of 9/30/84	Fiscal year 1985 appropriation
1. Etiologic agent and cofactors:		
a. Discovery:		
CDC	$ 3,330	—
NIH:		
NCI	1,373	—
NINCDS	355	—
Total	5,058	—
b. Confirmation and extension of observations on causative agent and discovery of role of coinfections and cofactors:		
ADAMHA	1,036	$ 685
CDC	1,403	3,210
NIH:		
DRR	71	95
NCI	3,929	8,058
NEI	25	150
NHLBI	483	422
NIAID	785	1,184
Total	7,732	13,804
2. Development and evaluation of blood tests:		
a. Development:		
CDC	650	1,244
NIH:		
DRR	7	9
NCI	111	203
NHLBI	302	298
Total	1,070	1,754
b. Evaluation:		
CDC	471	1,018
FDA	—	3,270
NIH:		
NHLBI	555	195
NINCDS	40	86
Total	1,066	4,569
3. Surveillance:		
CDC	2,732	4,335
NIH:		
NCI	40	65
Total	2,772	4,400
4. Epidemiological studies (to determine natural history of AIDS):		
ADAMHA	688	648
CDC	2,710	4,068
NIH:		
DRR	1	—
NCI	4,098	5,177
NEI	19	135
NHLBI	3,513	7,044
NIAID	8,449	6,788
NINCDS	122	259
Total	19,600	24,119
5. Development and evaluation of vaccine (including animal model):		
CDC	500	516
FDA	—	4,660
NIH:		
NCI	1,582	4,955
NIAID	706	1,458
NINCDS	91	187
Total	2,879	11,776
6. Studies of therapeutic intervention:		
a. AIDS		
FDA	798	895
NIH:		
DRR	132	222
NCI	1,759	2,817
NHLBI	—	800
NIAID	1,113	3,117
NIDR	—	206
NINCDS	50	101
Total	3,852	8,158
b. Opportunistic infections:		
CDC	250	186
NIH:		
DRR	274	244
NCI	170	298
NEI	16	15
NIAID	4,124	4,725
NIDR	81	—
NINCDS	42	86
Total	4,957	5,554
7. Immunologic studies:		
CDC	300	32
NIH:		
DRR	121	167
NCI	2,612	3,695
NIAID	3,720	5,345
NIDR	—	205
Total	6,753	9,444
8. Psychosocial factors:		
ADAMHA	1,067	1,479
NIH:		
DRR	4	5
NIAID	34	34
NINCDS	—	431
Total	1,105	1,949
9. Simian AIDS:		
NIH:		
DRR	746	989
NCI	850	1,403
NIAID	183	154
NINCDS	810	—
Total	2,589	2,546
10. Prevention of transfusion-related AIDS:		
CDC	500	707
NIH:		
NCI	22	50
NHLBI	—	125
Total	522	882
11. Bioethics and biosafety:		
CDC	54	124
NIH:		
NCI	10	20
NHLBI	18	—
Total	82	144
12. Information dissemination/public affairs:		
CDC	850	3,260
NIH:		
NCI	71	110
NIAID	502	457
Total	1,423	3,827
PHS Total	$61,460	$92,926[b]

Notes:

[a] Source: E. N. Brandt, Jr., Assistant Secretary for Health, Public Health Service, U.S. Department of Health and Human Services, Washington, DC, letter to Office of Technology Assessment, U.S. Congress, Dec. 20, 1984.

[b] Excluding $4.5 million for CDC virology lab. Includes $8.3 million for FDA which has not yet been obligated.

ments, and that planning for AIDS activities has been impeded by the rapidly changing problem of AIDS and related investigations rather than by inadequate resources, although "perhaps planning could have been improved if resource availability had been known at the onset."

PHS agencies also commented on the five "open issues" that OTA identified in the introduction to this section. With respect to the first issue, the extent to which progress in other disease areas has suffered as a result of diversions to AIDS activities, the comment from PHS was that "other disease areas have not necessarily suffered as a result of the increased emphasis being planned on AIDS" and that "what we learn from AIDS will have significant importance in other areas, with far-reaching benefits for our research on numerous disease conditions." Further, the NIH will be able to fund 1,500 more new and competing research grants (for a total of 6,500) with its fiscal year 1985 appropriation, providing "momentum across the entire research base."[1]

Commenting on the second issue, the wisdom of limiting the priority status of AIDS primarily to biological research, Assistant Secretary Brandt stated that "the effort has never been exclusively limited to this priority." He pointed out that only about half of ADAMHA's AIDS activities in fiscal year 1985 will be for biomedical research and that the AIDS activities of CDC primarily support nonbiomedical research activities (i.e., laboratory investigations, surveillance, epidemiologic studies, technology transfer, information dissemination, and programs on disease prevention and control). He also stated, however, that "a concerted effort in public education or in areas such as psychosocial factors cannot take place until we have discovered, through biomedical research, the answers we must have to the numerous questions involving this puzzling disease."

As for the manner in which limited resources can be allocated among agencies, the response from PHS was that because Congress appropriates funds by agency, PHS does not have the ability to reprogram funds between its agencies. Nevertheless, the Assistant Secretary noted, PHS has consistently placed a high priority on AIDS. NIH, for example, has allocated approximately $9 million of its fiscal year 1985 appropriation increases to expand AIDS activities.

Assistant Secretary Brandt's response to the problem of personnel ceilings in PHS agencies was that while personnel resources are always limited and difficult decisions must be made, "careful management" can "minimize the impact on science and other AIDS activities." The Assistant Secretary further noted, with respect to the problems NCI and NIAID are experiencing, that "there is . . . a provision for exceptions to be granted by the Director, NIH, to these restrictions for high-priority needs. AIDS is considered a high priority."

Finally, with regard to the issue of the extent to which PHS agencies will be able to pursue AIDS work adequately in the face of further cutbacks, the PHS response was that "it is difficult to predict any actions to be taken in the future," but "as long as AIDS continues to be a high priority health problem, PHS will continue to assign it a high priority and allocate the necessary resources for its support." Assistant Secretary Brandt pointed out that at NIH there has been a 42-percent increase for AIDS from 1984 to 1985, as compared to a 14-percent increase in total appropriations for the seven participating institutes. Greater increases for AIDS research relative to non-AIDS activities, Brandt noted, are apparent at "most" of the other agencies.

OTA concludes that although PHS has indeed undertaken a massive effort and made significant accomplishments, the statement that AIDS is DHHS's number one health priority has not always been supported by financial and personnel resources. The responsibility for this situation, however, appears not to rest with the Office of the Assistant Secretary in PHS, but instead to reflect decisions made at higher levels of the Federal Government. The Administration has not pursued an appropriation for the Public Health Emergency Act, choosing instead to rely on securing appropriations for individual PHS agencies from Congress. Although insufficient and uncertain distribution of resources has not been the sole cause of delays or inadequacies in PHS AIDS research, surveillance, and service provision, it has resulted in at least inadequate planning, increased competitiveness among agencies, inadequate attention to certain areas which are perceived by many to be important (e.g., public education and prevention), and a diversion of attention from other critical health areas.

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[1] Subsequent to the Assistant Secretary's letter, it was reported that the Office of Management and Budget (OMB) plans to reduce NIH's fiscal year 1985 competing grants from 6,526 to 5,000 by obligating funds for 1,526 grants in fiscal year 1985 but not actually spending the money until fiscal year 1986 (*FDC Reports* ("The Blue Sheet") 1:P&R-1, Jan. 9, 1985).

RELATED ISSUES

This memorandum is primarily focused on the biomedical questions surrounding AIDS and the ways in which PHS has attempted to address these questions. Several related issues that also deserve mentioning, however, are those that involve confidentiality and informed consent, prevention of AIDS through education on the risk factors associated with the disease, and financing for the clinical and supportive services that AIDS patients require.

Confidentiality and Informed Consent

AIDS has been described as a "legal emergency" as well as a medical crisis (49). Much of the concern centers on discrimination experienced by members of high-risk groups, especially gay men and intravenous drug abusers (124). (Private consensual homosexual activity is illegal in 23 States and the District of Columbia (17).) There have been reports of discrimination in housing, employment, health or life insurance coverage, or in the receipt of medical or dental care, not only against AIDS patients but also against those thought to have AIDS.

Two sections of the Public Health Service Act have been used to protect confidentiality in federally sponsored research. Section 242a of the act (42 U.S.C. section 242a) authorizes the Secretary of DHHS to protect the privacy of individuals participating in research on mental health, including research on the use and effect of alcohol and other psychoactive drugs, by: 1) withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals; and 2) prohibiting persons authorized to protect the privacy of such individuals from being compelled to identify them in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. (Thus, for example, section 242a has been used to protect the confidentiality of participants in NIAID's five-city study of the natural history of AIDS.)

Section 242m(d) of the Public Health Service Act (42 U.S.C. section 242 m(d)) provides that information may not be used for any purpose other than the purpose for which it was supplied unless consent has been given. Assurances of confidentiality based on this section were issued by CDC in July 1984 to cover the agency's surveillance work, and epidemiologic studies and studies of transfusion-related AIDS are being reviewed by CDC for possible application of section 242m(d) to these areas.

These two sections of the Public Health Service Act apparently cannot cover all AIDS research. Section 242a applies only to mental health research or research into drug or alcohol use. Section 242m(d) is applicable only to the Centers specified in the statute (i.e., the National Center for Health Statistics, the National Center for Health Services Research, and the National Center for Health Care Technology). CDC has applied section 242m(d) to its surveillance activities, because they are similar to the functions and purposes of the activities carried on by the National Center for Health Statistics and because both CDC and the National Center for Health Statistics are funded in the same way (113).

These limitations of existing statutory assurances of confidentiality have led to a proposal by the National Gay Task Force and Lambda Legal Defense and Education Fund to expand section 242m(d) to cover AIDS-related research and surveillance undertaken directly or indirectly by PHS

(113). The need for such a statute will increase if members of high-risk groups fail to present themselves as research subjects (as some gay organizations have advised), fearing breaches of confidentiality.

Closely linked to concerns over confidentiality is the issue of informed consent. For example, the National Gay Task Force has stated that if confidentiality is to have any real meaning, researchers must contractually obligate themselves to the research subject not to disclose identifying information, and that this objective can be accomplished by requiring the researcher to use a strong consent form containing such a guarantee (113).

Until assurances of confidentiality can be given for all AIDS-related research, informed consent may require that research subjects be told that such assurances cannot be guaranteed. This was an issue in drafting the consent form for the NHLBI study in which serum samples of 200,000 voluntary blood donors are being collected so that they can be tested for the presence of antibodies to HTLV-III. The wording in the informed consent document that was forwarded to the Institutional Review Boards of the blood centers involved in the study and whose use PHS recommended, was as follows: "Only authorized staff of this institution and members of the research team are expected to have access to the information relative to my test; however, officials of the Food and Drug Administration or others authorized by law may require access to this information" (167).

Another informed consent issue that arose in drafting the consent document for the NHLBI blood donor study was the significance of a positive test for the presence of antibodies to HTLV-III. (As stated earlier in this memorandum, aside from indicating exposure to HTLV-III, the implications neither of a positive test nor of a negative test are known.) The document that was sent to the blood centers for their use stated: "The significance of the presence of the antibodies and the reliability of the method used to detect them are not known at this time. If my blood is tested and *if these antibodies are detected, I will be informed of the results and offered further testing to clarify their meaning*" (emphasis in original) (167).

One commentator has concluded that the uncertainty surrounding the blood test meant that "neither respect for persons nor beneficence allows us currently to disclose the antibody test results to the subject or others. Research subjects should be promised a detailed explanation of their status when that information is validated" (116). Other commentators, assuming that it would violate the same set of ethical principles (respect for persons and beneficence) for research subjects or blood donors to remain unaware of the information, despite its uncertain implications, have described the disclosure of HTLV-III antibody test results as a question of "how," not "if" (4,37).

Blood banking and commercial plasmapheresis organizations are currently grappling with the social and ethical issues surrounding the imminent availability of the blood test. One concern is that if the test is initially available only at blood banks and plasmapheresis centers, gay men will present themselves as donors in order to learn the results of the tests on their blood. Because of the dangers to the blood supply and the added expenses of screening and not using blood that tests positively for antibodies to HTLV-III, there have been suggestions that the test be made available at a low cost through health centers in high-risk areas.

The questions for blood banks are many. Should registries of HTLV-III antibody-positive donors be maintained? Should donors be listed separately as HTLV-III positive, or should they be aggregated with others deferred for different health reasons? What should recipients of blood products from donors who are HTLV-III antibody positive be told? (See previous box on PHS recommendations for screening blood and plasma donations for recommendations on notification and confidentiality. These recommendations were addressed by an ad hoc group convened jointly by The Hastings Center, a bioethics organization, and the American Blood Commission in January 1985 (5).)

Other concerns about the blood test involve its potential use by employers, the military, the immigration service, health insurers or others. Should a private insurer, for example, be allowed to use a positive test result as evidence for denial of benefits because AIDS was a "pre-existing condition"? Should a positive result be the basis for the dismissal or transfer of a food handler or the transfer of a prisoner to an isolated section of the prison?

A task force convened by The Hastings Center recently reviewed Federal, State, and local statutes as they applied to information gathered for use in AIDS treatment, research, surveillance, and scientific and program audits. One of its conclusions was that "administrative and statutory safeguards should be created at Federal and State levels to prevent both unjustifiable voluntary and involuntary disclosure of personally identifiable data." The task force found that "(t)he strength of State and local protections . . . is unknown, since they have not been challenged in court by Federal authorities" (10). Its report also contains specific recommendations on institutional policies regarding who should have access to what kinds of data; what kinds of patient identifiers would be appropriate; how to balance the tensions between the desire for confidentiality and public health reporting requirements; and what degree of variability in these policies is appropriate across various legal jurisdictions, research institutions, and public health bodies.

The Office of Protection from Research Risks (OPRR) is the NIH agency responsible for overseeing human subjects research. In general, the policy of OPRR is to provide to local Institutional Review Boards guidance on informed consent procedures, rather than to establish central Federal direction, or models of informed consent forms (98). Officials from OPRR have stated, however, that legislation providing guarantees of confidentiality might begin to be considered.

Prevention Through Education

In spite of the discovery of the probable cause of AIDS, prevention through education remains the primary means of restricting the spread of this disease. Effective treatment and especially prevention of infection through vaccines represent difficult technical objectives yet to be achieved.

PHS has focused its educational efforts on physicians and other health professionals, leaving education of high-risk groups largely up to the leadership of the groups themselves. (Appendix D provides details about PHS public information activities.)

Efforts at direct public education have included the AIDS hotline, the *Facts About AIDS* newsletter, partial funding of a public television documentary, NIH radio programs, a videotape about AIDS, periodic announcements by DHHS Secretary Heckler, and the publication of booklets (147,148). The most direct advice on risk reduction has been published by CDC in two sets of interagency prevention recommendations, the latest in anticipation of the blood test to detect antibodies to HTLV-III (153,159; see box 2-B below for precautions recommended by PHS for individuals likely to have an HTLV-III infection). Reprints of PHS interagency precautions have been distributed to community health centers, other health facilities and drug treatment centers. NIDA has reprinted AIDS materials and generated materials of its own for distribution to drug abuse treatment and counseling centers.

Efforts directed at health professionals include CDC's conferences for health care professionals and State health agencies. CDC is cosponsoring a major international conference on AIDS in April 1985 with nearly a thousand participants expected. PHS has developed videotapes and a booklet (149) directed to health care workers and others who might come in contact with AIDS patients as a consequence of their employment (e.g., court officers, prison officials, morticians). NIMH is developing a booklet on *Mental Health Implications of AIDS*, and its Center for Prevention Research cosponsored a meeting on the Psychosocial Aspects of AIDS in December 1984. NIAID has established an outreach program to transmit the latest technical advances in AIDS research to primary care physicians and allied health personnel. State and local health agencies in particular have played a role in distributing information about AIDS, including advice about prevention, to their communities. A DHHS-funded U.S. Conference of Mayors' survey of local, mostly government, groups found that 40 percent of the material distributed had been prepared by the Federal Government (143).

Perhaps the most controversial aspect of prevention through public education has been the

Box 2-B.—PHS Recommendations for Individuals Likely To Have an HTLV-III Infection

An individual judged most likely to have an HTLV-III infection should be provided the following information and advice:

1. The prognosis for an individual infected with HTLV-III over the long-term is not known. However, data available from studies conducted among homosexual men indicate that most persons will remain infected.
2. Although asymptomatic, these individuals may transmit HTLV-III to others. Regular medical evaluation and follow-up is advised, especially for individuals who develop signs or symptoms suggestive of AIDS.
3. Refrain from donating blood, plasma, body organs, other tissue, or sperm.
4. There is a risk of infecting others by sexual intercourse, sharing of needles, and possibly, exposure of others to saliva through oral-genital contact or intimate kissing. The efficacy of condoms in preventing infection with HTLV-III is unproven, but the consistent use of them may reduce transmission.
5. Toothbrushes, razors, or other implements that could become contaminated with blood should not be shared.
6. Women with a seropositive test, or women whose sexual partner is seropositive, are themselves at increased risk of acquiring AIDS. If they become pregnant, their offspring are also at increased risk of acquiring AIDS.
7. After accidents resulting in bleeding, contaminated surfaces should be cleaned with household bleach freshly diluted 1:10 in water.
8. Devices that have punctured the skin, such as hypodermic and acupuncture needles, should be steam sterilized by autoclave before reuse or safely discarded. Whenever possible, disposable needles and equipment should be used.
9. When seeking medical or dental care for intercurrent illness, these persons should inform the individuals responsible for their care of their positive antibody status so that appropriate evaluation can be undertaken and precautions taken to prevent transmission to others.
10. Testing for HTLV-III antibody should be made available to individuals who may have been infected as a result of their contact with a seropositive person (e.g., sexual partners, persons with whom needles have been shared, infants born to seropositive mothers). Revised recommendations will be published as additional information becomes available and additional experience is gained with this test.

Reported by Centers for Disease Control; Food and Drug Administration; Alcohol, Drug Abuse, and Mental Health Administration; National Institutes of Health; Health Resources and Services Administration.

SOURCE: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, "Provisional Inter-Agency Recommendations for Screening Donated Blood and Plasma for Antibody to the Virus Causing Acquired Immunodeficiency Syndrome," *Morbidity and Mortality Weekly Report* 34:1-5, Jan. 11, 1985.

provision of advice to gay men and intravenous drug abusers. One reason may be that providing advice on preventive practices may be viewed as condoning bisexuality, homosexuality, or intravenous drug abuse. Another has been that not enough was known to support definitive guidelines. Too, there is some concern that gay men may be wary of advice from the Federal Government, believing it to stem from a bias against homosexuals or to be based on insufficient medical knowledge (76). Despite remaining questions, there are preventive measures to which all parties agree. The use of condoms, while not assuredly protective against AIDS transmission, does provide some protection against sexually transmitted diseases. Likewise, the use of disposable or sterilized rather than shared or otherwise contaminated needles for intravenous drug use will almost certainly reduce transmission. These considerations are mentioned very briefly in the PHS brochure aimed at gay and bisexual men (148) and are mentioned more explicitly in the recent PHS

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recommendations. Brochures designed by gay organizations (69,112,128) have provided much more explicit and practical advice on the relative safety of various sexual practices.

Rather than funding local groups directly, PHS has funded the U.S. Conference of Mayors to act, among other things, as a distribution channel for PHS-developed materials. The Conference of Mayors' role has been expanded to provide risk reduction and blood test information through gay community groups. Fiscal year 1984 appropriations provided $150,000 to be used for prevention projects of community groups; funding decisions for specific projects will be made in early calendar year 1985 (75). Fiscal year 1985 funding for the Conference is anticipated to be $200,000. In addition, CDC is expanding its support of research to evaluate education efforts (e.g., changes in sex practices and number of partners, changes in drug use) by both private and public groups, a research area which NIMH is also supporting.

As noted earlier, about 4 percent of the PHS AIDS budget (exclusive of the Office of Public Affairs in OASH) for fiscal year 1985 was allocated to public education, compared to 2 percent in fiscal year 1984 (see tables 17 and 18). One need found by the U.S. Conference of Mayors' survey of local governments was for training and technical assistance in the community, particularly on safe sex guidelines and the blood test (143). One critic of PHS's budget priorities questions the top priority given to research, sees research and public education working hand-in-hand, with each less effective without the other, and concludes that in the absence of effective interventions and treatment therapies, the only option at this point is prevention of the disease (92). Furthermore, a representative of the National Gay Task Force has stated (88): "The PHS knows how to target its message to specific audiences—using the gay media would be no different but for the fear of being associated too directly with the gay community . . . if the PHS is going to make a conscious decision to leave prevention education to us, they should at least provide some funding." Finally, one AIDS researcher has observed (99a): "There is an immense job left to do in public education about AIDS risk. This need will certainly become more evident and acute as the disease moves outside of existing risk groups and into the general population in the next 2 years. At that time, continued education will be needed for those in the risk groups about limiting contagion, as well as for the general population in order to prevent hysteria and give the public concrete recommendations as to how to reduce risk of contraction. It would be helpful if Federal funding sources anticipate this trend and plan for such funding."

Financing of Clinical and Supportive Services

Questions on financing of the clinical and supportive services for AIDS patients and who should be responsible for such financing have arisen repeatedly. It has been estimated that the cost of caring for an average AIDS patient from diagnosis to death is about $60,000 to $70,000 (109,117).

The Social Security Administration has two programs which provide Federal assistance for those disabled through illness. Both programs apply to those who are unable to work because of a physical or mental disability expected to last at least 12 months or result in death. One program, Disability Insurance (Title II), is for those who have paid into Social Security; the other, Supplemental Security Income, is for those who have not paid enough into Social Security. These tests can usually be met by AIDS patients. However, other factors complicate the process of meeting eligibility requirements for financial assistance and of obtaining coverage for clinical and supportive care. First, there have been criticisms that the use of the relatively conservative surveillance definition of AIDS by CDC has delayed needed financial assistance for patients not meeting this definition of AIDS (83). Second, Federal and State insurance programs generally reimburse for established and standard treatments, while the most important and promising treatments for opportunistic infections in AIDS are still in the experimental stage (117). Finally, although admission to a hospice might be appropriate or desired by some AIDS patients, recently promulgated reimbursement regulations require that physicians certify that their patients are not expected to live more than 6 months before the Federal Government will reimburse for care (24).

Additionally, the question remains as to which, if any, government entities—local, State, or Federal—should be responsible for or share in covering the expenses that AIDS patients cannot meet either directly or through their health insurance coverage (123). PHS's potential contribution to services coverage is limited, if not nonexistent. Thus, discussions about possible Federal assistance must include other entities in DHHS, such as the Health Care Financing Administration.

CONCLUSIONS

Accumulating evidence indicates that the recently discovered retrovirus HTLV-III is the basic cause of AIDS. As more has been learned about HTLV-III's ability to cause disease, it has become apparent that a broad spectrum of immunologic and clinical responses can occur. Some persons have been infected with few or no immunologic abnormalities and no evidence of illness, others have had severe effects on their immune systems and developed fulminant and inevitably fatal AIDS, while others have manifested responses between these two extremes. Associated risk factors are under examination and will help in understanding why some people are able to resist infection while others progress to different stages of clinical illness.

Rapid advances in knowledge about HTLV-III are being made possible because of previous knowledge of the existence of a closely related retrovirus (HTLV-I), recent advances in understanding the functioning of our immune systems, the availability of recombinant DNA technologies, and tests based on immunologic and recombinant DNA principles. The new knowledge about HTLV-III has led to an expanded and increasingly precise cataloging of methods that might be applied against HTLV-III and associated infections and tumors found in AIDS, and some methods, such as drugs that might inhibit infection, are already being tried in limited clinical trials. On the other hand, the discovery of HTLV-III as the primary cause of AIDS can also be seen as only the beginning of focused efforts to control AIDS, and it remains to be seen whether the knowledge that is gained can be used to develop effective vaccines and therapeutic drugs within a few years.

Although DHHS has designated AIDS as its number one health priority, in terms of financial support, this priority has been implemented at PHS and not at the Department level. The Department's position has been that funds for AIDS activities should be transferred from other PHS activities, and increases in funding for AIDS activities have come at the initiative of Congress, not from DHHS. This has also been the case for personnel ceilings, with personnel allocated to AIDS activities within the overall ceilings imposed by OMB on DHHS, which in turn allocates personnel levels to PHS and its agencies.

The question of whether AIDS funds should come out of existing PHS agency budgets or whether such funds should augment agency budgets is related to perceptions about: 1) whether AIDS-related research is part of the overall missions of the PHS agencies involved, and 2) whether the AIDS epidemic is a sufficiently unique and growing public health problem that it requires additional resources. PHS agencies are involved precisely because their basic activities are relevant to AIDS research, which also promises to extend our understanding of immune mechanisms and the causes of cancer. Such research is attracting many researchers for purposes in addition to finding a solution to the AIDS problem. The issue, therefore, is in deciding: 1) when other activities are being curtailed too much because of fund transfers from those activities to AIDS-related activities; 2) when AIDS-related activities are being delayed because of wrangling over how much funds are to be transferred and from which other activities; and 3) when such fund transfers become inadequate to fund AIDS-related activities. There is probably no way to reach a consensus on when these thresholds have been or will be reached.

Aside from the issue of fund transfers and their ability to meet AIDS-related research needs without substantially retarding research in other priority areas, the allocation of funds and the sources of those funds in themselves are important measures of priority-setting for addressing the AIDS problem. On this point, while PHS has reacted to OTA's assessment by stating that the funds PHS agencies have (including appropriations voted by Congress and resisted by DHHS) are adequate (22), PHS had previously asked for additional funds (20), two NCI advisory bodies have stated that more funds are needed (163,176), and numerous Federal and non-Federal researchers have privately told OTA that additional funds and personnel have been needed.

Another consideration that pertains to the adequacy of resources devoted to AIDS-related research is that research and development are going on internationally and within both the public and private sectors. Thus, an examination of PHS's contribution to AIDS-related research provides an incomplete picture of the extent of activities and resources devoted to addressing the AIDS epidemic. However, PHS's activities are laying down much of the foundation, and PHS investigators have been indispensable and are extensively involved in collaborations with non-Federal researchers both nationally and internationally.

In contrast to AIDS-related research which is international and involves both for-profit and nonprofit investigators, there are other AIDS-related activities that are domestic in nature and which involve public health policy. These activities involve issues which could not be addressed extensively within this memorandum primarily on the biology of AIDS, but which were of sufficient importance to be identified and raised briefly—namely, prevention of AIDS through education, financing of clinical and supportive services for AIDS patients, and assurances of confidentiality and informed consent.

Although significant advances have been made in understanding AIDS, its primary cause, and associated factors, it will be some time before this biomedical knowledge can be expected to be translated into effective preventive and therapeutic interventions. In the interim, and probably even if biological remedies become available, prevention through education on ways of minimizing exposure to HTLV-III has the greatest potential of limiting the spread of AIDS. So far, efforts to prevent AIDS through education have received minimal funding, especially efforts targeted at the groups at highest risk.

Providing and assisting in paying for clinical and supportive services is already a significant problem in those areas of the country with relatively large numbers of AIDS patients. This situation will worsen as the number of AIDS patients increases and if new treatments prolong life but do not restore health. The Federal response to date has focused on the biomedical research aspects of AIDS; thus, PHS has been given the primary responsibility for AIDS-related activities. Increasing demands for Federal support are inevitable, but the potential contribution of PHS agencies to providing and financing service needs is severely limited by the nature of their responsibilities. Thus, if the Federal Government is to respond to the service needs of AIDS patients, Federal activities will have to expand beyond those attributable to PHS and at a minimum involve other organizational units within DHHS. The allocation of responsibility between Federal, State, and local governments will also have to be determined, and legislation defining the Federal responsibility will most likely have to be enacted.

A final related issue identified in this memorandum is that of confidentiality and informed consent, first arising in the context of treatment of AIDS patients and participation in AIDS-related research projects, and soon to be a major concern as tests for evidence of exposure or infection to HTLV-III become generally available. Confidentiality safeguards can be improved without sacrificing the surveillance needs of public health officials and data sharing among researchers. Informed consent will be an especially difficult issue, because the first tests to be applied will detect exposure to HTLV-III through the presence or absence of antibodies. However, persons who test positive will not be able to know whether they are actually carriers of HTLV-III, whether they will develop AIDS, or whether they are not infected and will remain well.

Appendixes

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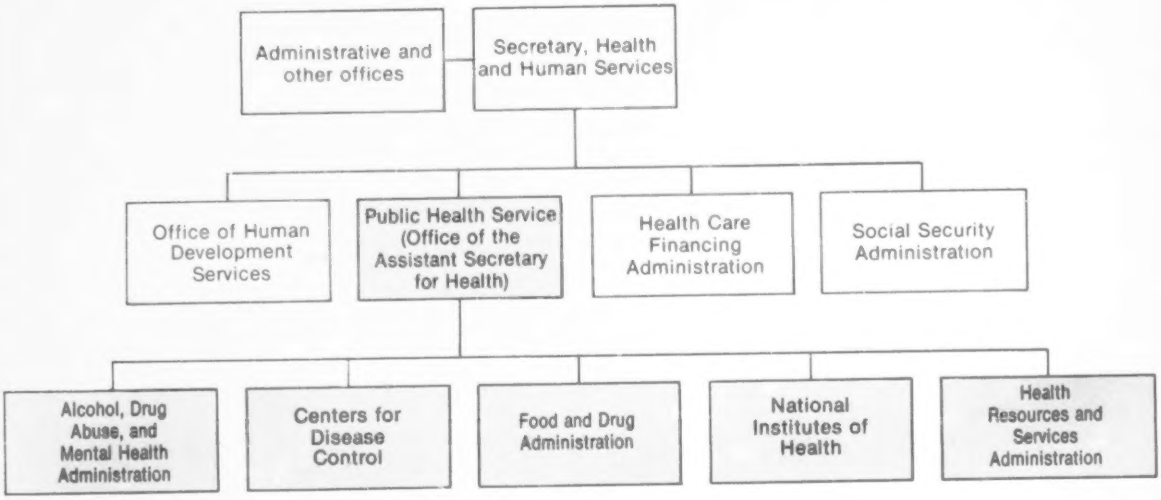
Appendix B.—PHS Organization Chart


Administrative and other offices
Secretary, Health and Human Services
Office of Human Development Services
Public Health Service (Office of the Assistant Secretary for Health)
Health Care Financing Administration
Social Security Administration
Alcohol, Drug Abuse, and Mental Health Administration
Centers for Disease Control
Food and Drug Administration
National Institutes of Health
Health Resources and Services Administration

SOURCE: Office of Technology Assessment.

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Appendix C.—OASH Summary of Individual PHS Agencies' Obligations for AIDS Activities, Fiscal Years 1984 and 1985

The tables in this appendix show estimated fiscal year 1984 and 1985 obligations for AIDS activities for the Public Health Service (PHS) and for each of the PHS agencies listed below:

- Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA).
- Centers for Disease Control (CDC).
- Food and Drug Administration (FDA).
- National Institutes of Health (NIH):
  —Division of Research Resources,
  —National Cancer Institute,
  —National Eye Institute,
  —National Heart, Lung, and Blood Institute,
  —National Institute of Allergy and Infectious Diseases,
  —National Institute of Dental Research, and
  —National Institute of Neurological and Communicative Disorders and Stroke.

The tables in this appendix were provided to OTA by W. H. Little, Office of the Assistant Secretary for Health (OASH), Public Health Service, U.S. Department of Health and Human Services. OASH obtained the figures in these tables from individual agencies.

1/04/85

AIDS
PUBLIC HEALTH SERVICE TOTAL
(dollars in thousands)

AGENCY		FY 1984 APPROPRIATION	FY 1984 OBLIGATION AS OF 9/30/84	FY 1985 APPROPRIATION	FY 1985 OBLIGATION AS OF 12/31/84	FY 1985 OBLIGATION AS OF 3/31/85	FY 1985 OBLIGATION AS OF 6/30/85	FY 1985 OBLIGATION AS OF 9/30/85
ADAMHA		2,961	2,791	2,812	-	-	-	-
CDC		13,750	13,750	18,700	-	-	-	-
FDA		798	798	8,825	-	-	-	-
NIH	DRR	1,175	1,356	1,731	-	-	-	-
NIH	NCI	16,588	16,627	26,851	-	-	-	-
NIH	NEI	58	60	300	-	-	-	-
NIH	NHLBI	4,890	4,871	8,884	-	-	-	-
NIH	NIAID	19,068	19,616	23,262	-	-	-	-
NIH	NIDR	30	81	411	-	-	-	-
NIH	NINCDS	1,547	1,510	1,150	-	-	-	-
NIH		43,356	44,121	62,589	-	-	-	-
PHS	TOTAL	60,865	61,460	92,926	-	-	-	-

1/04/85

AIDS
ALCOHOL, DRUG ABUSE, & MENTAL HEALTH ADMINISTRAION
(dollars in thousands)

	FY 1984		FY 1985				
	APPROPRIATION	OBLIGATION AS OF 9/30/84	APPROPRIATION	OBLIGATION AS OF 12/31/84	OBLIGATION AS OF 3/31/85	OBLIGATION AS OF 6/30/85	OBLIGATION AS OF 9/30/85
1. Etiologic Agent and Co-factors:	-	-	-	-	-	-	-
a. Discovery	-	-	-	-	-	-	-
b. Confirmation and extension of observations on causative agent and discovery of role of co-infections and co-factors	1,206	1,036	685	-	-	-	-
2. Development & Evaluation of Blood Tests:	-	-	-	-	-	-	-
a. Development	-	-	-	-	-	-	-
b. Evaluation	-	-	-	-	-	-	-
3. Surveillance	-	-	-	-	-	-	-
4. Epidemilogical Studies (to Determine Natural History of AIDS)	688	688	648	-	-	-	-
5. Development and Evaluation of Vaccine (including Animal Model)	-	-	-	-	-	-	-
6. Studies of Therapeutic Intervention:	-	-	-	-	-	-	-
a. AIDS	-	-	-	-	-	-	-
b. Opportunistic Infections	-	-	-	-	-	-	-
7. Immunologic Studies	-	-	-	-	-	-	-
8. Psychosocial Factors	1,067	1,067	1,479	-	-	-	-
9. Simian AIDS	-	-	-	-	-	-	-
10. Prevention of Transfusion-related AIDS	-	-	-	-	-	-	-
11. Bioethics and Biosafety	-	-	-	-	-	-	-
12. Information Dissemination/ Public Affairs	-	-	-	-	-	-	-
AGENCY TOTAL	2,961	2,791	2,812	-	-	-	-

1/04/85

AIDS
CENTERS FOR DISEASE CONTROL
(dollars in thousands)

	FY 1984		FY 1985				
	APPROPRIATION	OBLIGATION AS OF 9/30/84	APPROPRIATION	OBLIGATION AS OF 12/31/84	OBLIGATION AS OF 3/31/85	OBLIGATION AS OF 6/30/85	OBLIGATION AS OF 9/30/85
1. Etiologic Agent and Co-factors:	-	-	-	-	-	-	-
a. Discovery	3,330	3,330	-	-	-	-	-
b. Confirmation and extension of observations on causative	-	-	-	-	-	-	-
agent and discovery of role of co-infections and co-factors	1,403	1,403	3,210	-	-	-	-
2. Development & Evaluation of Blood Tests:	-	-	-	-	-	-	-
a. Development	650	650	1,244	-	-	-	-
b. Evaluation	471	471	1,018	-	-	-	-
3. Surveillance	2,732	2,732	4,335	-	-	-	-
4. Epidemiological Studies (to Determine Natural History of AIDS)	2,710	2,710	4,068	-	-	-	-
5. Development and Evaluation of Vaccine (including Animal Model)	500	500	516	-	-	-	-
6. Studies of Therapeutic Intervention:	-	-	-	-	-	-	-
a. AIDS	-	-	-	-	-	-	-
b. Opportunistic Infections	250	250	186	-	-	-	-
7. Immunologic Studies	300	300	32	-	-	-	-
8. Psychosocial Factors	-	-	-	-	-	-	-
9. Simian AIDS	-	-	-	-	-	-	-
10. Prevention of Transfusion-related AIDS	500	500	707	-	-	-	-
11. Bioethics and Biosafety	54	54	124	-	-	-	-
12. Information Dissemination/ Public Affairs	850	850	3,260	-	-	-	-
AGENCY TOTAL	13,750	13,750	18,700	-	-	-	-

1/04/85

AIDS
FOOD AND DRUG ADMINISTRATION
(dollars in thousands)

	FY 1984		FY 1985				
	APPROPRIATION	OBLIGATION AS OF 9/30/84	APPROPRIATION	OBLIGATION AS OF 12/31/84	OBLIGATION AS OF 3/31/85	OBLIGATION AS OF 6/30/85	OBLIGATION AS OF 9/30/85
1. Etiologic Agent and Co-factors:	-	-	-	-	-	-	-
a. Discovery	-	-	-	-	-	-	-
b. Confirmation and extension of observations on causative	-	-	-	-	-	-	-
agent and discovery of role of co-infections and co-factors	-	-	-	-	-	-	-
2. Development & Evaluation of Blood Tests:	-	-	-	-	-	-	-
a. Development	-	-	-	-	-	-	-
b. Evaluation	-	-	3,270	-	-	-	-
3. Surveillance	-	-	-	-	-	-	-
4. Epidemiological Studies (to Determine Natural History of AIDS)	-	-	-	-	-	-	-
5. Development and Evaluation of Vaccine (including Animal Model)	-	-	4,660	-	-	-	-
6. Studies of Therapeutic Intervention:	-	-	-	-	-	-	-
a. AIDS	798	798	895	-	-	-	-
b. Opportunistic Infections	-	-	-	-	-	-	-
7. Immunologic Studies	-	-	-	-	-	-	-
8. Psychosocial Factors	-	-	-	-	-	-	-
9. Simian AIDS	-	-	-	-	-	-	-
10. Prevention of Transfusion-related AIDS	-	-	-	-	-	-	-
11. Bioethics and Biosafety	-	-	-	-	-	-	-
12. Information Dissemination/ Public Affairs	-	-	-	-	-	-	-
AGENCY TOTAL	798	798	8,825	-	-	-	-

1/04/85

AIDS
NATIONAL INSTITUTES OF HEALTH
(dollars in thousands)

	FY 1984		FY 1985				
	APPROPRIATION	OBLIGATION AS OF 9/30/84	APPROPRIATION	OBLIGATION AS OF 12/31/84	OBLIGATION AS OF 3/31/85	OBLIGATION AS OF 6/30/85	OBLIGATION AS OF 9/30/85
1. Etiologic Agent and Co-factors:	-	-	-	-	-	-	-
a. Discovery	1,976	1,728	-	-	-	-	-
b. Confirmation and extension of observations on causative agent and discovery of role of co-infections and co-factors	6,033	5,293	9,909	-	-	-	-
2. Development & Evaluation of Blood Tests:	-	-	-	-	-	-	-
a. Development	413	420	510	-	-	-	-
b. Evaluation	410	595	281	-	-	-	-
3. Surveillance	40	40	65	-	-	-	-
4. Epidemiological Studies (to Determine Natural History of AIDS)	15,129	16,202	19,403	-	-	-	-
5. Development and Evaluation of Vaccine (including Animal Model)	2,628	2,379	6,600	-	-	-	-
6. Studies of Therapeutic Intervention:	-	-	-	-	-	-	-
a. AIDS	3,341	3,054	7,263	-	-	-	-
b. Opportunistic Infections	4,782	4,707	5,368	-	-	-	-
7. Immunologic Studies	5,598	6,453	9,412	-	-	-	-
8. Psychosocial Factors	34	38	470	-	-	-	-
9. Simian AIDS	2,682	2,589	2,546	-	-	-	-
10. Prevention of Transfusion-related AIDS	22	22	175	-	-	-	-
11. Bioethics and Biosafety	28	28	20	-	-	-	-
12. Information Dissemination/ Public Affairs	240	573	567	-	-	-	-
AGENCY TOTAL	43,356	44,121	62,589	-	-	-	-

1/04/85

AIDS
DIVISION OF RESEARCH RESOURCES
(dollars in thousands)

	FY 1984		FY 1985				
	APPROPRIATION	OBLIGATION AS OF 9/30/84	APPROPRIATION	OBLIGATION AS OF 12/31/84	OBLIGATION AS OF 3/31/85	OBLIGATION AS OF 6/30/85	OBLIGATION AS OF 9/30/85
1. Etiologic Agent and Co-factors:	-	-	-	-	-	-	-
a. Discovery	-	-	-	-	-	-	-
b. Confirmation and extension of observations on causative	-	-	-	-	-	-	-
agent and discovery of role of co-infections and co-factors	-	71	95	-	-	-	-
2. Development & Evaluation of Blood Tests:	-	-	-	-	-	-	-
a. Development	-	7	9	-	-	-	-
b. Evaluation	-	-	-	-	-	-	-
3. Surveillance	-	-	-	-	-	-	-
4. Epidemiological Studies (to Determine Natural History of AIDS)	201	1	-	-	-	-	-
5. Development and Evaluation of Vaccine (including Animal Model)	-	-	-	-	-	-	-
6. Studies of Therapeutic Intervention:	-	-	-	-	-	-	-
a. AIDS	122	132	222	-	-	-	-
b. Opportunistic Infections	122	274	244	-	-	-	-
7. Immunologic Studies	-	121	167	-	-	-	-
8. Psychosocial Factors	-	4	5	-	-	-	-
9. Simian AIDS	730	746	989	-	-	-	-
10. Prevention of Transfusion-related AIDS	-	-	-	-	-	-	-
11. Bioethics and Biosafety	-	-	-	-	-	-	-
12. Information Dissemination/ Public Affairs	-	-	-	-	-	-	-
INSTITUTE TOTAL	1,175	1,356	1,731	-	-	-	-

1/04/85

AIDS
NATIONAL CANCER INSTITUTE
(dollars in thousands)

	FY 1984		FY 1985				
	APPROPRIATION	OBLIGATION AS OF 9/30/84	APPROPRIATION	OBLIGATION AS OF 12/31/84	OBLIGATION AS OF 3/31/85	OBLIGATION AS OF 6/30/85	OBLIGATION AS OF 9/30/85
1. Etiologic Agent and Co-factors:	-	-	-	-	-	-	-
a. Discovery	1,373	1,373	-	-	-	-	-
b. Confirmation and extension of observations on causative agent and discovery of role of co-infections and co-factors ..	3,929	3,929	8,058	-	-	-	-
2. Development & Evaluation of Blood Tests:	-	-	-	-	-	-	-
a. Development	111	111	203	-	-	-	-
b. Evaluation	-	-	-	-	-	-	-
3. Surveillance	40	40	65	-	-	-	-
4. Epidemiological Studies (to Determine Natural History of AIDS)	4,098	4,098	5,177	-	-	-	-
5. Development and Evaluation of Vaccine (including Animal Model)	1,543	1,582	4,955	-	-	-	-
6. Studies of Therapeutic Intervention:	-	-	-	-	-	-	-
a. AIDS	1,759	1,759	2,817	-	-	-	-
b. Opportunistic Infections	170	170	298	-	-	-	-
7. Immunologic Studies	2,612	2,612	3,695	-	-	-	-
8. Psychosocial Factors	-	-	-	-	-	-	-
9. Simian AIDS	850	850	1,403	-	-	-	-
10. Prevention of Transfusion-related AIDS	22	22	50	-	-	-	-
11. Bioethics and Biosafety	10	10	20	-	-	-	-
12. Information Dissemination/ Public Affairs	71	71	110	-	-	-	-
INSTITUTE TOTAL	16,588	16,627	26,851	-	-	-	-

1/04/85

AIDS
NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE
(dollars in thousands)

	FY 1984		FY 1985				
	APPROPRIATION	OBLIGATION AS OF 9/30/84	APPROPRIATION	OBLIGATION AS OF 12/31/84	OBLIGATION AS OF 3/31/85	OBLIGATION AS OF 6/30/85	OBLIGATION AS OF 9/30/85
1. Etiologic Agent and Co-factors:	-	-	-	-	-	-	-
a. Discovery	603	355	-	-	-	-	-
b. Confirmation and extension of observations on causative agent and discovery of role of co-infections and co-factors	-	-	-	-	-	-	-
2. Development & Evaluation of Blood Tests:	-	-	-	-	-	-	-
a. Development	-	-	-	-	-	-	-
b. Evaluation	-	40	86	-	-	-	-
3. Surveillance	-	-	-	-	-	-	-
4. Epidemiological Studies (to Determine Natural History of AIDS)	-	122	259	-	-	-	-
5. Development and Evaluation of Vaccine (including Animal Model)	-	91	187	-	-	-	-
6. Studies of Therapeutic Intervention:	-	-	-	-	-	-	-
a. AIDS	-	50	101	-	-	-	-
b. Opportunistic Infections	-	42	86	-	-	-	-
7. Immunologic Studies	-	-	-	-	-	-	-
8. Psychosocial Factors	-	-	431	-	-	-	-
9. Simian AIDS	944	810	-	-	-	-	-
10. Prevention of Transfusion-related AIDS	-	-	-	-	-	-	-
11. Bioethics and Biosafety	-	-	-	-	-	-	-
12. Information Dissemination/ Public Affairs	-	-	-	-	-	-	-
INSTITUTE TOTAL	1,547	1,510	1,150	-	-	-	-

Appendix D.—Individual PHS Agencies' and OASH Office of Public Affairs' Anticipated AIDS-Related Grants and Activities, Fiscal Year 1985 and NIH AIDS Projects Funded in Fiscal Years 1983 and 1984

This appendix provides information about AIDS-related grants and activities as follows:

- Section 1: Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) anticipated fiscal year 1985 grants and activities:
  - —National Institute of Mental Health (NIMH), and
  - —National Institute on Drug Abuse (NIDA).
- Section 2: Centers for Disease Control (CDC) anticipated fiscal year 1985 grants and activities.
- Section 3: Food and Drug Administration (FDA) anticipated fiscal year 1985 grants and activities.
- Section 4: National Institutes of Health (NIH) anticipated fiscal year 1985 activities:
  - —National Cancer Institute,
  - —National Heart, Lung, and Blood Institute
  - —National Institute of Dental Research,
  - —National Institute of Neurological and Communicative Disorders and Stroke,
  - —National Institute of Allergy and Infectious Diseases,
  - —National Eye Institute, and
  - —Division of Research Resources.
- Section 5: NIH AIDS projects funded in fiscal years 1983 and 1984.
- Section 6: Office of the Assistant Secretary for Health (OASH) Office of Public Affairs AIDS Public Information Plan for fiscal year 1985.[1]

The information in this appendix was provided to OTA by the agencies themselves.

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[1] Also includes descriptions of public information activities of NIH, NIDA, NIMH, and CDC.

1/04/85

AIDS
NATIONAL EYE INSTITUTE
(dollars in thousands)

	FY 1984		FY 1985				
	APPROPRIATION	OBLIGATION AS OF 9/30/84	APPROPRIATION	OBLIGATION AS OF 12/31/84	OBLIGATION AS OF 3/31/85	OBLIGATION AS OF 6/30/85	OBLIGATION AS OF 9/30/85
1. Etiologic Agent and Co-factors:	-	-	-	-	-	-	-
a. Discovery	-	-	-	-	-	-	-
b. Confirmation and extension of observations on causative agent and discovery of role of co-infections and co-factors	23	25	150	-	-	-	-
2. Development & Evaluation of Blood Tests:	-	-	-	-	-	-	-
a. Development	-	-	-	-	-	-	-
b. Evaluation	-	-	-	-	-	-	-
3. Surveillance	-	-	-	-	-	-	-
4. Epidemilogical Studies (to Determine Natural History of AIDS)	18	19	135	-	-	-	-
5. Development and Evaluation of Vaccine (including Animal Model)	-	-	-	-	-	-	-
6. Studies of Therapeutic Intervention:	-	-	-	-	-	-	-
a. AIDS	-	-	-	-	-	-	-
b. Opportunistic Infections	17	16	15	-	-	-	-
7. Immunologic Studies	-	-	-	-	-	-	-
8. Psychosocial Factors	-	-	-	-	-	-	-
9. Simian AIDS	-	-	-	-	-	-	-
10. Prevention of Transfusion-related AIDS	-	-	-	-	-	-	-
11. Bioethics and Biosafety	-	-	-	-	-	-	-
12. Information Dissemination/ Public Affairs	-	-	-	-	-	-	-
INSTITUTE TOTAL	58	60	300	-	-	-	-

1/04/85

AIDS
NATIONAL HEART, LUNG AND BLOOD INSTITUTE
(dollars in thousands)

	FY 1984		FY 1985				
	APPROPRIATION	OBLIGATION AS OF 9/30/84	APPROPRIATION	OBLIGATION AS OF 12/31/84	OBLIGATION AS OF 3/31/85	OBLIGATION AS OF 6/30/85	OBLIGATION AS OF 9/30/85
1. Etiologic Agent and Co-factors:	-	-	-	-	-	-	-
a. Discovery	-	-	-	-	-	-	-
b. Confirmation and extension of observations on causative agent and discovery of role of co-infections and co-factors	489	483	422	-	-	-	-
2. Development & Evaluation of Blood Tests:	-	-	-	-	-	-	-
a. Development	302	302	298	-	-	-	-
b. Evaluation	410	555	195	-	-	-	-
3. Surveillance	-	-	-	-	-	-	-
4. Epidemilogical Studies (to Determine Natural History of AIDS)	3,671	3,513	7,044	-	-	-	-
5. Development and Evaluation of Vaccine (including Animal Model)	-	-	-	-	-	-	-
6. Studies of Therapeutic Intervention:	-	-	-	-	-	-	-
a. AIDS	-	-	800	-	-	-	-
b. Opportunistic Infections	-	-	-	-	-	-	-
7. Immunologic Studies	-	-	-	-	-	-	-
8. Psychosocial Factors	-	-	-	-	-	-	-
9. Simian AIDS	-	-	-	-	-	-	-
10. Prevention of Transfusion-related AIDS	-	-	125	-	-	-	-
11. Bioethics and Biosafety	18	18	-	-	-	-	-
12. Information Dissemination/ Public Affairs	-	-	-	-	-	-	-
INSTITUTE TOTAL	4,890	4,871	8,884	-	-	-	-

1/04/85

AIDS
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
(dollars in thousands)

	FY 1984		FY 1985				
	APPROPRIATION	OBLIGATION AS OF 9/30/84	APPROPRIATION	OBLIGATION AS OF 12/31/84	OBLIGATION AS OF 3/31/85	OBLIGATION AS OF 6/30/85	OBLIGATION AS OF 9/30/85
1. Etiologic Agent and Co-factors:	-	-	-	-	-	-	-
a. Discovery	-	-	-	-	-	-	-
b. Confirmation and extension of observations on causative agent and discovery of role of co-infections and co-factors	1,592	785	1,184	-	-	-	-
2. Development & Evaluation of Blood Tests:	-	-	-	-	-	-	-
a. Development	-	-	-	-	-	-	-
b. Evaluation	-	-	-	-	-	-	-
3. Surveillance	-	-	-	-	-	-	-
4. Epidemiological Studies (to Determine Natural History of AIDS)	7,141	8,449	6,788	-	-	-	-
5. Development and Evaluation of Vaccine (including Animal Model)	1,085	706	1,458	-	-	-	-
6. Studies of Therapeutic Intervention:	-	-	-	-	-	-	-
a. AIDS	1,460	1,113	3,117	-	-	-	-
b. Opportunistic Infections	4,443	4,124	4,725	-	-	-	-
7. Immunologic Studies	2,986	3,720	5,345	-	-	-	-
8. Psychosocial Factors	34	34	34	-	-	-	-
9. Simian AIDS	158	183	154	-	-	-	-
10. Prevention of Transfusion-related AIDS	-	-	-	-	-	-	-
11. Bioethics and Biosafety	-	-	-	-	-	-	-
12. Information Dissemination/ Public Affairs	169	502	457	-	-	-	-
INSTITUTE TOTAL	19,068	19,616	23,262	-	-	-	-

1/04/85

AIDS
NATIONAL INSTITUTE OF DENTAL RESEARCH
(dollars in thousands)

	FY 1984		FY 1985				
	APPROPRIATION	OBLIGATION AS OF 9/30/84	APPROPRIATION	OBLIGATION AS OF 12/31/84	OBLIGATION AS OF 3/31/85	OBLIGATION AS OF 6/30/85	OBLIGATION AS OF 9/30/85
1. Etiologic Agent and Co-factors:	-	-	-	-	-	-	-
a. Discovery	-	-	-	-	-	-	-
b. Confirmation and extension of observations on causative agent and discovery of role of co-infections and co-factors	-	-	-	-	-	-	-
2. Development & Evaluation of Blood Tests:	-	-	-	-	-	-	-
a. Development	-	-	-	-	-	-	-
b. Evaluation	-	-	-	-	-	-	-
3. Surveillance	-	-	-	-	-	-	-
4. Epidemiological Studies (to Determine Natural History of AIDS)	-	-	-	-	-	-	-
5. Development and Evaluation of Vaccine (including Animal Model)	-	-	-	-	-	-	-
6. Studies of Therapeutic Intervention:	-	-	-	-	-	-	-
a. AIDS	-	-	206	-	-	-	-
b. Opportunistic Infections	30	81	-	-	-	-	-
7. Immunologic Studies	-	-	205	-	-	-	-
8. Psychosocial Factors	-	-	-	-	-	-	-
9. Simian AIDS	-	-	-	-	-	-	-
10. Prevention of Transfusion-related AIDS	-	-	-	-	-	-	-
11. Bioethics and Biosafety	-	-	-	-	-	-	-
12. Information Dissemination/ Public Affairs	-	-	-	-	-	-	-
INSTITUTE TOTAL	30	81	411	-	-	-	-

SECTION 1: Alcohol, Drug Abuse, and Mental Health Administration Anticipated AIDS-Related Grants and Activities, Fiscal Year 1985:
National Institute of Mental Health
National Institute on Drug Abuse

NATIONAL INSTITUTE OF MENTAL HEALTH

FISCAL YEAR 1984

Extramural Research

During FY 1984 NIMH continued and expanded its research support for projects focused on the psychiatric, behavioral and psychosocial aspects of AIDS. This resulted in a portfolio of 14 research projects, totaling $1,204,838. These projects focus on relationships between psychological conditions and immune function, development and testing of psychological and behavioral measures to assess mental health status as it relates to AIDS, changes in high risk behavior patterns, as well as studies which supplement ongoing NIH research to correlate behavioral changes with immunological status in large samples over time.

NIMH funding has allowed investigators to develop and improve inventories which measure psychosocial and mental health aspects of AIDS in groups at risk and those with confirmed cases of AIDS. In one study, preliminary results of assessments of the mental health of those at risk suggest the tendency for scores on some measures to be poorer than expected. These tentative results require confirmation and further research to determine their implications. It has been hypothesized that increased levels of depression, helplessness, and anxiety correlate with behavior changes in this population. Such inventories, with modifications, may be valuable in identifying individuals at risk for life-threatening illness beyond the AIDS epidemic. Results may have implications for prevention and therapeutic intervention.

An NIMH-supported study is conducting neuropsychological evaluations of AIDS patients to assess differences between psychological reactions to the disease and cerebral problems resulting from the disease process which may also effect mood, cognition and behavior. It has been recognized that clinically significant alterations in these functions may be overlooked until patients become disruptive or incapacitated.

In another NIMH supported study of the impact of AIDS on psychological functioning, preliminary results indicate that the mere experience of being at risk increased anxiety levels for eventually contracting the disease.

The AIDS patient, like patients with other life threatening illnesses, struggles with the fear of imminent death, the necessity for abrupt closure on future plans, and the challenge to maintain a purpose. Knowledge of these factors is necessary to develop effective intervention strategies.

It is hoped that such research will assist in identifying those persons most at risk for the development of AIDS, and will be helpful in providing recommendations for both prevention and educational programs.

NIMH research will continue to focus on understanding the needs of these individuals, along the continuum of disease related events, as well as to identify those psychological and behavioral factors which may negatively or positively influence the course of illness. Other research related to immune function and psychiatric disorders, and the interplay between psychoactive drugs and immune function is also encouraged and supported by the NIMH.

A more detailed description of projects currently receiving NIMH support is attached. (Attachment 1)

Intramural Research

Dr. David Rubinow of the Biological Psychiatry Branch, NIMH, is collaborating with other NIH researchers to assess neuropsychiatric dysfunction in patients with AIDS. The purpose of this study is to obtain longitudinal neuropsychiatric evaluations of patients with AIDS.

Educational and Related Activities

The Mental Health Education Branch, Division of Communication and Education, NIMH, is developing a booklet for health caregivers on Mental Health Implications of AIDS. The manuscript, which is currently undergoing clearance, deals with the emotional reactions of AIDS patients and the mental health implications for their families, friends, and associates. It discusses the emotional involvement of caregivers working with terminally ill patients as well as concerns regarding contagion and related issues.

Four NIMH staff members recently received PHS awards for their participation in the PHS AIDS hotline activities.

FISCAL YEAR 1985

During FY 1985, NIMH will continue to support research focused on the behavioral and psychological aspects of AIDS. NIMH will expand its research efforts to include an emphasis on psychological reactions of individuals as a function of receiving information concerning blood test results. NIMH is encouraging research on the psychological reactions to learning HTLV-III results.

Additional research areas which NIMH seeks to support include: changing patterns of intimacy and behaviors among high-risk populations; relationships between immune function and mental health status, such as depression, anxiety, suicide attempts, and other responses to high levels of stress; interventions prior to or during the course of the disease; and studies of psychological factors that impede participation in either research or treatment programs. A group of NIMH supported researchers is preparing an article which will focus on the psychosocial issues for patients and groups at risk. The article will be directed toward clinicians and will contain specific recommendations.

The NIMH Center for Prevention Research cosponsored a meeting on the Psychosocial Aspects of AIDS with the Institute for the Advancement of Health in New York City. (December 8-9, 1984.) This meeting focused on the psychological aspects of AIDS and involved numerous NIMH grantees. Principal investigators and other project staff from the NIMH funded projects studying the mental health implications of AIDS attended, along with other researchers, clinicians, PHS representatives, and others involved in research on the psychosocial aspects of AIDS.

The meeting was organized to provide the AIDS researchers with an opportunity to exchange information and to address future research needs and policy issues related to the mental health aspects of AIDS. Participants explored how psychosocial factors may affect immune system function, how emotional stress may affect the course of disease, and how behavioral interventions may optimize functioning of the immune system. Other broad topics included the psychological consequences of events along the continuum of disease and treatment and the potential for psychosocial interventions which could improve both physical and emotional status. Researchers also shared strategies and advice regarding issues of sampling, measurement, outcomes, and policy recommendations. In addition, the group discussed issues related to the forthcoming HTLV-III antibody blood test.

A psychosocial inventory appropriate for the assessment of psychosocial variables in homosexual populations, developed by an NIMH-supported researcher, is currently being made available to other investigators in the U.S. and Europe.

NIMH-supported researchers and staff will also participate in the International Conference on AIDS to be held in Atlanta, Georgia, April 14-17, 1985. ADAMHA is a cosponsor of the conference.

Publications and Presentations

During FY1985, research supported by NIMH was cited in several news releases and in Public Health Service Reports. In addition, the November 1984 issue of the American Psychologist contained articles describing three NIMH supported research projects as follows:

"Coping with the Threat of AIDS", Jill Joseph, et al, MH 39346-01

"Behavioral and Psychological Factors in AIDS", Martin and Vance, MH 39557-01

"Psychological Research is Essential to Understanding and Treating AIDS", Coates, Temoshok, Mandel, MH 39344-01

Applied Methodology: A Primer of Pitfalls and Opportunities in AIDS Research, Jane Zich and Lydia Temoshok (in press, Praeger, N.Y.), Book Chapter, MH 39344-01

AIDS and Sexual Behavior Reported by Men in San Francisco, Leon McKusick, William Horstman, Thomas Coates, (in press, American Journal of Public Health), MH 39553-01

NIMH researchers presented at numerous conferences and workshops including:

A symposium on AIDS at the University of California, May 4-5, 1984

A workshop on statistical problems at the Lakeshore VA Medical Center in Chicago, Illinois, on August 28, 1984

A symposium on AIDS at the Annual Meeting of the American Psychological Association, August 28, 1984

A conference on AIDS at Northwestern University Medical School on December 1, 1984

A conference on psychological aspects of AIDS in Glen Cove, New Jersey, December 7-9, 1984

Future Symposium: A Symposium on AIDS at the Society of Behavioral Medicine Sixth Annual Meeting

FISCAL YEAR 1986

NIMH will continue to support research relevant to the behavioral and psychosocial aspects of AIDS. It is anticipated that studies will focus on stress factors related to the blood test to identify the HTLV III virus in blood donors and high risk populations. There will be a continuing need for public education for persons at high risk, families and friends, and health care workers as more specific information becomes available.

New directions in research, prevention, and public education programs will be determined by an examination of research findings and information generated by workshops and the International Conference.

NIMH will continue to coordinate its activites in this area with ADAMHA and appropriate NIH institutes.

RESEARCH GRANTS

Investigator: Lydia Temoshok, Ph.D. (1 R01 MH 39344-01)
Institution: University of California, San Francisco
Title: A Longitudinal Psychosocial Study of AIDS Patients

In FY 83, Dr. Temoshok received a two year grant to study psychological and behavioral consequences of having suspected or diagnosed AIDS. Immunological functions of subjects will be correlated with clinical and psychological conditions to study relationships of psychological factors, the immune system, and physical illness.

Investigator: Jill Joseph, Ph.D. (1 R01 MH 39346-01)
Institution: University of Michigan
Title: Coping Strategies in AIDS Patients

This research focuses on developing and testing psychological and behavioral measures used in AIDS research. Specifically, the investigator hopes to: (a) study the relationships among psychosocial variables and measures of immune function and physical health; (b) quantify the extent of changes in sexual behavior that are presumed to affect an individual's risk for contracting AIDS; (c) examine factors associated with the maintenance or impairment of psychological and social functioning in response to the threat of an epidemic of fatal illness.

Investigator: Karolynn Siegel, Ph.D. (1 R01 MH 39551-01)
Institution: Memorial Hospital for Cancer, New York, New York
Title: AIDS Risk Groups: Predicting Changes in Sexual Practices

This study attempts to identify psychosocial factors associated with changes in sexual and drug related practices of AIDS patients and those at risk for AIDS, and the extent to which they comply with treatment or monitoring regimens. Factors to be examined include: social support, self-esteem, anxiety, depression, and perceived risks. The sample population will include asymptomatic homosexual males not diagnosed with AIDS or lymphadenopathy, homosexual men with generalized lymphadenopathy, and homosexual male AIDS patients.

Investigator: Marcus A. Conant, M.D. (1 R01 MH 39553-01)
Institution: University of California, San Francisco
Title: Impact of AIDS on Sexual Behavior of Gay Men

This study assesses changes over time related to the social and psychological functioning regarding high risk sexual behaviors, health behaviors, intimacy patterns, and psychiatric symptoms. Dependent measures will be examined in the context of knowledge of health guidelines, sources and modes of receiving information, personal beliefs about AIDS transmission, attitudes and behaviors regarding intimacy patterns, and individual differences in psychological reaction to the AIDS crisis.

Investigator: Carole S. Vance, Ph.D. (1 RO1 MH 39557-01)
Institution: Columbia University, New York, New York
Title: Mental Health Effects of AIDS on At Risk Homosexual Men

This study is assessing the mental health and behavioral effects of the epidemic of AIDS on homosexual males (700) who do not have AIDS, but are at high risk. Data will be collected through two face-to-face interviews. The methodology will include both retrospective and prospective components. Outcome measures will be specific and non-specific psychological distress, drug use, and sexual behavior.

Investigator: Thomas Coates, Ph.D. (1 RO1 MH 39343-01A1)
Institution: University of California, San Francisco
Title: Prospective Psychosocial Study in Men at Risk for AIDS

This study is a collaborative effort with a contract funded by NIAID entitled "A Prospective Sero-Epidemiological Study of AIDS in Homosexual Men Residing in San Francisco". Under the NIAID study a probability sample of disease free single males (1000 homosexual and 200 heterosexual) 25-54 years of age will be recruited; it is estimated that between 45-75 cases of AIDS will develop during a four year follow-up. Each subject will receive a physical examination and donate specimens for serological, virological, and chemical study. The NIMH portion will address: (1) the psychosocial and behavioral risk factors for AIDS; (2) the attitudes, behaviors, and beliefs of the cohort over time; (3) psychosocial consequences of diagnosis of AIDS or of symptoms possibly associated with later development of AIDS; and (4) exploration of psychoneuroimmunological relationships.

Investigator: Christopher Coe, Ph.D. (1 RO1 MH/NS 40144-01)
Institution: Stanford University
Title: Psychological Stress and Immune Responsiveness

This project will investigate the development of a nonhuman primate model for assessing the effects of psychologically induced stress on immune responses. The research will document the qualitative and quantitative effects of elevated cortisol levels on basic immune parameters in separated maternal and newly weaned.

Investigator: Mark Laudenslager, Ph.D. (1-R03-MH-39316-01)
Institution: University of Denver
Title: Coping and Immune Function

This research will provide parametric data on the time course and long term effects of prior experiences with controllable or uncontrollable shock on immune system function. Approximately 400 laboratory rats will be used.

Investigator: Mark Laudenslager, Ph.D. (5R01 MH37373-02)
Institution: University of Denver
Title: Loss and Separation: Immune Status

This is the second year of a project to study the effects of separation of mother and offspring on immune system and behavior in primates. Affective disorders are frequently preceded by important separation and new data indicate that separation and losses are etiologically significant antecedents of a variety of nonpsychiatric medical disorders. The project will carry out a comprehensive series of experiments to study the effects of separation and loss on the function of the immune system.

Investigator: Steven Schleifer, M.D. (1 R01 39651-01)
Institution: Mt. Sinai School of Medicine
Title: Major Depressive Disorder and Immune Function

This project will investigate the association between clinical depression and immunity. Immune function will be examined in drug free patients with mild and severe depressive disorders and compared with matched controls, mediated depressed subjects, and patients in remission. The research could contribute substantially to understanding ways in which the central nervous system regulates immunity.

Investigator: Rosa T. Canoso, M.D. (R01-MH-39528-01)
Institution: U.S. Veterans Administration Hospital (Mass.)
Title: Chlorpromazine Immunogenetics and Tardive Dyskinesia

This research is focused on a study of the association of chlorpromazine treatment and the production of autoimmune antibodies. The study is one of the first examples of the involvement of autoantibodies in major psychoses. The prevalence and severity of tardive dyskinesia will be correlated with the presence of antibodies. Follow-up studies will determine changes in the immunoneurological, neurological, or psychological parameters after discontinuation of chlorpromazine.

Investigator: Richard Pillard, M.D. (2-R01-MH-32170-0A1S1)
Institutions: Boston University
Title: Clinical and Family Study of Sexual Orientation

This research is focused on the study of the familial and clinical aspects of homosexuality. It will document psychiatric disorders in homosexuals, family patterns of homosexuality, and gender-specific attributes of behavior. The research may provide a basis for further studies of genetic, hormonal, or longitudinal-developmental studies focused on the origins of sexual orientation.

Investigator: Stanley Zucker, M.D. (1-R01-MH-33684-01)
Institution: Veterans Administration Medical Center
Title: Chlorpromazine-Induced Immunopathy

This research is focused on the study of immunological abnormalities in schizophrenic patients who are treated with chlorpromazine. The objective is to characterize the natural history of chlorpromazine induced immunopathy on the mechanism of immune dysfunction. The research has significant implications regarding the long term safety of psychoactive drugs and the interaction of such drugs with the immune system.

Investigator: Robert Ader, Ph.D. (5 K05 MH 06318-15)
Institution: University of Rochester
Title: Psychoneuroimmunology

This research is focused on understanding the regulation of immune responses by behavioral processes operating through the control nervous system and the endocrine system. Documentation and elaboration of the relationship between the central nervous system and the immune system has potential consequences for understanding the immune processes and clinical implications concerning chemotherapy in treatment regimens. The capacity of conditioning to suppress or enhance immune responses raises issues regarding the modifiability of the immune system and the integration of biologic and psychologic function. The results will contribute to an understanding of psychoneuroimmunology and the adaptive process. Animal subjects (rats and mice) are used in this research.

NATIONAL INSTITUTE ON DRUG ABUSE

Data from CDC indicate that 18% of all cases of AIDS reported, to date, have occurred in heterosexual drug users. In addition, 14% of homosexuals with AIDS (comprising 9% of the total number of cases of AIDS) present with a history of parenteral drug use. Thus, independent of other risk factors, 27% of reported cases of AIDS occur in individuals with a history of parenteral drug use. In the New York-New Jersey metropolitan areas the percent of AIDS patients with a history of parenteral drug use is even greater. New New York City Department of Health reports that 66% of all cases of AIDS occur in individuals who have engaged in homosexual behavior, while in 32% of cases there is a history of self-administered parenteral drug use. Similar data are reported for New Jersey.

Past experience with diseases such as malaria and serum hepatitis has led investigators to hypothesize that HTLV-III is transmitted among parenteral drug users through the sharing of contaminated needles. The cultural practices of native born Haitians include frequent parenteral administration of "medicinal agents" ("picurist"). The needles used in these practices are frequently reused, without sterilization. These cultural practices have accompanied the Haitians who have migrated to the large urban centers in the United States, and may represent a mode of parenteral exposure to HTLV-III.

Drug abusers use substances which have intrinsic immunosuppressive properties and are associated with chromosomal damage. These substances are administered in a contaminated vehicle (nonsterile water) which contains contaminated diluents and impure narcotic. This mixture is self-administered through blood and dirt-contaminated unsterile needles. The question of whether this drug-taking behavior is able to produce sufficient insult to the immune system to enhance the pathological effects of HTLV-III on the host is the major target of the NIDA research effort.

NIDA's activities include:

A. Investigator: Des Jarlais, Don C., 1 R01 DA 03574
Institution: New York State Department of Health
Title: Risk Factors for AIDS Among Intravenous Drug Users
Project Year: Start Date: 9/83, 2 years

1. A group of drug-users who are indicted on various charges and who may acquire AIDS will be studied. Detailed questionnaires on lifestyle and drug-use, medical histories, immunologic function, HTLV/LAV antibody titres, and other factors will be measured. This group is unique in that they did not seek out treatment and may have unique variables--types of drug used, disease acquired, extent of disease.

2. A follow-up study design will be based on the cohort studies of the drug abuse populations. These studies will focus on changes in the individual's health to see what relationships exist between AIDS and the immunological status, virological profile, drug abuse life style or other identified factors. These will include a proportionate representation of the original groups studied.

3. Populations of patients in detox and methadone programs have been studied. Significant numbers of the detox, but not the methadone patients, have measureable LAV antibody titres (see report in July 13, 1984 MMWR). Interview data from detox subjects showed that exposure to the virus is associated with frequency of drug injection over the previous five years. The virus is relatively easy to spread among persons who inject illicit drugs. A follow-up of these individuals to determine the relationships of this virus to the development of AIDS and a study of all the various groups will be conducted in 1985-1986. These studies will include drug addicts and methadone subjects with and without AIDS, with and without LAV type virus, and with low to high T-helper/suppressor ratios.

B. Investigator: Hubbard
Institution: Research Triangle Institute, N.C.

A case-comparison study of AIDS patients with a history of intravenous heroin and cocaine use. The purpose of this study is to attempt to quantify the risk factors associated with needle-sharing and AIDS in geographically disparate cities. In addition, an attempt will be made to quantify the risk factor of the spouse and children living with needle-sharers. Physical examinations and immunochemistries will be used to assess health changes during the study. This study will be the first nationally based study to determine normative values for the more recently developed virological studies like HTLV among drug abusers. Attempts will be made to correlate the findings of this study with the clustering of AIDS in certain portions of the country. In addition, the presence and recurrence of other viral infections like herpes can be analyzed in terms of drug usage patterns. The hypothesis that several of the psychoactive substances may have immunosuppressive effects can be tested in a naturalistic setting.

C. Investigator: Cabral, G.A., 1 R01 DA 3647
Institution: Virginia Commonwealth University
Title: Effect of Cannabinoids on Vaginal Herpes 2 in the Guinea Pig
Project Year: Start Date: 7/84, 3 years

A preliminary study showed an increase in the severity of herpes-2 infection in guinea pigs administered THC and other cannabinoids. The researchers are investigating the effect of marijuana (THC) on the development of herpes-2 in guinea pigs in an attempt to determine if this effect is mediated by a drug action on the neurological, immunological, or an other system.

D. Investigator: Friedman, H., 1 R01 DA 3646
Institution: University of South Florida
Title: Marijuana Effects on Immunity
Project Year: Start Date: 4/84, 3 years

This is a study to examine the influence of marijuana components on both hormonal and cellular immune responses in vivo and in vitro. For example, they will measure the antibody formation by immune splenocytes or skin graft rejections, lymphocyte blastogenic responses, and lymphokine production.

E. Investigator: Falek, A., 5R01 DA 1451
Institution: Georgia Mental Health Institute
Title: Cellular Genetic Aspects of Opiate Use
Project Year: Start Date: FY 1984, 3 years

This is a study of the effects of narcotics on the immune system. This group is investigating the ability of lymphocytes of addicts as compared to normal subjects to form rosettes, the extent and duration of any alteration, mechanism of this effect and any genetic factors involved. This is an attempt to determine immmunological changes resulting from narcotic and other drug use.

F. Investigator: Watson, E.E., 1 R01 DA 03684
Institution: University of Mississippi
Title: Marijuana and Bacterial and Transplantation Immunity
Project Year: Start Date: 7/84, 3 years

The overall objective is to assess the potential immuno-suppressive effects of marijuana smoke through measures of dose-related increases in susceptibility to microbial infection and tumor growth in rats receiving marijuana smoke. Resistance to systemic as well as to localized infections will be assessed.

G. Investigator: Newmeyer, J.A., 1 R01 DA 03638
Institution: Community Substance Abuse Services
Title: Aids Risk Reduction for Needle-Using Drug Users
Year, Budget: Start date: 9/84, 1 year

It appears that public education programs in the homosexual community has increased an awareness of the role of lifestyle factors in predisposing towards AIDS. In certain large cities, it appears that this may be having a positive effect in decreasing the rate of increase of the disease among homosexuals. This effect has not been seen in the drug-abusing population. Funds are needed to develop methods to alert drug-abusers about the increased risk of AIDS associated with the use of intravenous drugs and to try to develop and evaluate new approaches to preventing drug abuse in those at risk for AIDS.

H. Joint NIDA-NCI Study

Recent epidemiologic evidence indicates that the putative agent HTLV-III can be transmitted by intimate sexual contact or by injection of contaminated blood, producing AIDS. As NCI now has a reliable and valid serologic assay for antibodies to HTLV-III, a seroprevalence study of serum antibodies to HTLV-III will be ascertained in drug users in the high risk area of the Newark SMSA. In addition, an attempt will be made to determine specific risk factors for contracting this newly identified virus. A second phase of this study, dependent on the results of the first phase of the implementation, will be an assessment of the actual risk of developing an AIDS-related illness in antibody positive and negative individuals. This prospective cohort study of drug users will attempt to determine the clinical relevance of an individual being HTLV-III positive.

SECTION 2: Centers for Disease Control Anticipated AIDS-Related Grants and Activities, Fiscal Year 1985

AIDS
CENTERS FOR DISEASE CONTROL

MAJOR FUNCTIONS	FUNDING PLAN-FY85	PROJECTS
1. Etiologic Agent and Co-factors:		
b. Confirmation & extension of observations on causative agent & discovery of role or co-infections and co-factors.	$ 3,210,000	1. Laboratory studies to characterize retroviruses implicated in AIDS. $756,700
		2. Laboratory studies on diagnosis of AIDS and development of tests. $1,806,650
		3. Studies on incidence, risk factors and natural history of AIDS. $556,650
2. Development & Evaluation of Blood Tests:		
a. Development	$1,244,000	1. Development of tests for opportunistic infections ocurring in AIDS. $63,000
		2. Characterization and development of tests for viral antigens found in AIDS patients. $1,181,000

MAJOR FUNCTIONS	FUNDING PLAN-FY85	PROJECTS
b. Evaluation	$1,018,000	1. Evaluation of tests and test combinations for sensitivity and specificity in the diagnosis of AIDS. $765,000
		2. Determination of incidence of viral antibodies in population groups at risk for AIDS. $253,000
3. Surveillance	$4,335,000	1. Conduct surveillance of various national and international population groups to better determine the prevalence of AIDS and risks of transmission. $169,000
		2. Conduct surveillance of AIDS and AIDS related complex among various risk group members their families and sexual partners. $306,000
		3. Determine the prevalence of retrovirus antibody and viremia in various U.S. populations including health care personnel exposed to potentially infected materials. $189,000
		4. National surveillance of AIDS including funding and monitoring "active" surveillance programs in 15 states/cities. $3,573,000
		5. Field investigations of AIDS cases without identifiable risk factors. $98,000

MAJOR FUNCTIONS	FUNDING PLAN-FY85	PROJECTS
4. Epidemiological Studies (to determine natural history of AIDS.	$4,068,000	1. Conduct various epidemiological studies of known risk group members, household members and sexual partners to better understand sources of infection, risk factors, and risk of transmission. $2,435,000
		2. Acquisition, including apheresis, processing, distribution and storage of AIDS and AIDS related specimens; Serum Bank AIDS collection inventory; data storage and retrieval. $334,000
		3. Conduct studies of the relationship between AIDS and lymphadenopathy syndrome in various populations including families of AIDS patients. $397,000
		4. Multifacted field and epidemiologic investigations of AIDS in foreign countries with AIDS to better understand prevalence risk factors and transmissiblity. $366,000
		5. Continue studies of pathogenesis of HTLV-III/LAV infection in chimpanzees and search for other animal models. $128,000
		6. Provide seriologic and biologic laboratory support for AIDS epidemiologic studies. $408,000

MAJOR FUNCTIONS	FUNDING PLAN-FY85	PROJECTS
5. Development & Evaluation of Vaccine (including animal model)	$ 516,000	1. Determination of antibody induction properties of viral antigens found in AIDS patients. $516,000
6. Studies of Therapeutic Intervention:		
b. Opportunistic Infections	$ 186,000	1. Studies on the effectiveness of certain IND drugs for opportunistic infections in AIDS patients. $186,000
7. Bioethical & Biosafety Issues	$ 124,000	1. Studies on required precautions when handling potentially infective (AIDS) materials. $124,000
8. Information Dissemination/Public Affairs	$3,260,000	1. Consult, develop and disseminate information to health workers treating patients with AIDS. $68,000
		2. Information/Health Education/risk reduction activities such as the PHS hotline, public information program; Conference of Mayors National Information interchange system; International Conference; Laboratory Training Course and public and professional information. $850,000
		3. Establish contracts and cooperative agreements with State/local health departments for AIDS prevention programs. $2,342,000

MAJOR FUNCTIONS	FUNDING PLAN-FY85	PROJECTS
9. Immunologic Studies	$ 32,000	Inventory and production of reagents used for immunologic testing in AIDS patients. $32,000
12. Prevention of Transfusion-Related AIDS	$ 707,000	1. Epidemiological studies and surveillance of AIDS patients in whom the use of blood or blood products is implicated as a causative mechanism. $707,000

SECTION 3: Food and Drug Administration Anticipated AIDS-Related Grants and Activities, Fiscal Year 1985

FOOD AND DRUG ADMINISTRATION
AIDS-Related Activities
Fiscal Year 1985
(\$ in 000s)[a]

Evaluation of Blood Test	
Facilities renovation	\$ 150
Blood contracts[b]	2,000
Supplies	150
Equipment	350
Personnel	620
Subtotal	\$3,270
Development and Evaluation of Vaccine	
Facilities renovation	\$ 300
Animal maintenance	1,150
Supplies	350
Equipment	1,300
Personnel	1,560
Subtotal	\$4,660
Studies of Therapeutic Intervention	
Personnel	\$ 895
Total FDA AIDS Activities - Fiscal Year 1985	\$8,825

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a. Sources: N. William, Center for Drugs and Biologics, and J. Biviano, Budget Analyst, Food and Drug Administration, Public Health Service, U. S. Department of Health and Human Services, Bethesda, Md., personal communications, Jan. 8, 1985.

b. Two extramural studies are planned, each for approximately \$1,000,000: One to assess the impact of testing on the whole blood and plasma supplies to determine which groups to exclude from donating; and a second to assess the past and current HTLV-III exposure of hemophiliacs who received antihemophiliac factor from pooled plasma donations.

SECTION 4: National Institutes of Health Anticipated AIDS-Related Activities, Fiscal Year 1985

REPORT ON AIDS RESEARCH

INTRODUCTION

In its report on the fiscal year 1985 budget for the Department of Health and Human Services, the Committee on Appropriations stated:

> With the recent discovery of the likely cause of AIDS and the ability to mass produce the HTLV-III virus, the Committee is informed that the Public Health Service will be able to move ahead in the development of a rapid blood test and a vaccine.
>
> While the budget request provides an additional $6 million for AIDS research at NIH, that request could not have factored in the recent important discoveries related to the cause of AIDS.
>
> Further, the Committee understands that NIH is currently reviewing its additional resource requirements for AIDS research in blood testing, HTLV-III production, vaccine development, monocyte abnormalities, and immune abnormalities; collaborative therapy trials of AIDS using standard protocols; clinical study related to treatment and prevention of AIDS; and epidemiological studies including possible HTLV-III infections in health care workers.
>
> The Committee believes that within the overall increases recommended in this bill for NIH, sufficient resources will be available to meet these additional research requirements. With that in mind, the Committee requests NIH to provide to the Committee by September 1 a report identifying, by Institute, the additional funding needed to respond to the recent AIDS discoveries, together with a description of activities to be conducted in FY 1985. (House Report No. 98-911, pages 33-34)

The following report has been prepared by the National Institutes of Health of the Department of Health and Human Services in response to the Committee's request.

Six NIH institutes and the Division of Research Resources are participating in the effort to conquer the AIDS problem — an effort that has been intensified by recent scientific breakthroughs. NIH has established an Executive Committee to coordinate the research efforts on AIDS.

FUNDING FOR AIDS RESEARCH

For FY 1984, NIH estimates that approximately $43,356,000 will be obligated in AIDS research through NIH-supported programs. This funding includes about $36,806,000 available in the regular appropriation and $6,550,000 provided by the Congress through a supplemental bill.

Preliminary estimates for AIDS funding in the 1985 President's Budget totalled $40,316,000. With the discovery of the causative agent, however, and with the availability of data on more recent funding experience, NIH now estimates that about $45,663,00 would be obligated within the level of resources provided by the President's Budget.

The recent appropriation for 1985 would provide for an estimated total of $62,164,000 for AIDS research to be conducted and supported by NIH. Approximately $11 million of this $16.5 million increase over the President's Budget was achieved through mechanism redistribution of the House and Senate allowances.

The attached table summarizes NIH funding for NIH research by Institute.

AIDS RESEARCH ACTIVITIES, FY 1985

The identification of the retrovirus HTLV-III as the cause of AIDS and the development of a process to produce this virus in large quantities have provided new impetus in the fight against this serious public health emergency. The NIH is intensifying its efforts to facilitate the development of a vaccine and to expand research on the natural history, epidemiology, accessory etiologic factors, pathogenesis, and animal models, prevention, and therapeutic methods. The specific avenues of research being undertaken by each of the participating institutes and the Division of Research Resources are discussed below.

National Cancer Institute

In 1985, the NCI will pursue new research projects to develop effective strategies for dealing with AIDS, not only through the use of currently available drugs and biological response modifiers in patients affected with the disease, but also through basic research to develop the knowledge necessary to prevent and cure the syndrome.

Efforts will primarily be directed toward the current commitment to basic laboratory research, important clinical research to determine whether interventive measures may be feasible, and continued vaccine developmental research. Additional focus will involve studies on the etiopathogenesis of the disease, including definitive studies on modes of transmission; the nature of the protective antibody and a clear immunological identification of the patient antibody profile. Additional knowledge is needed at the level of viral genes, which involves cloning and DNA sequencing.

A number of drugs will be tested both in vitro and in vivo in attempts to ameliorate or perhaps cure ongoing AIDS. Additional treatment protocols, such as inoculation with compatible protective lymphocytes, will be considered.

The NCI will expand its efforts in vaccine development. Past experience in the area of attempted retroviral vaccines has shown that exceptional care and expertise will be needed in the successful development of an HTLV-III vaccine. Furthermore, the parameters of retroviral growth and antigenic configuration are more complex than in the previously studied viruses. The result is that extensive vaccine developmental research will be required before a vaccine can actually be developed, and several general methods of vaccine production will be considered.

In the intramural research program, further work will be conducted on human cell lines that produce large amounts of HTLV-III; studies to define the molecular structure of DNA clones of HTLV-III; the determination of biologically critical parts of viral genome at the molecular level; the development of rapid immunological assays to detect infection by identifying virus or viral antigens; the development of other ways to halt AIDS progression; and an expanded search for a safe, effective therapy for AIDS and its related diseases.

Support will be increased for the NCI Frederick Cancer Research Facility, which is the prime source for HTLV-III production, the entire early scale-up into fermentation, and the transfer after exponential expansion into the for-profit sector for testing blood antibodies.

Other research efforts that will be undertaken include: nutritional assessment and support of AIDS patients, since wasting and cachexia are serious clinical problems that have not been adequately studied in these patients; study of "differentiating agents" and low-dose chemotherapy in AIDS patients with malignancy; considerations of new treatment modalities, including a number of agents that interfere with the general features of the retroviral life cycle, such as inhibitors of reverse transcriptase; studies on the immunologic effects of cytotoxic chemotherapy; and expanded grant support for the further development of animal models for AIDS.

National Heart, Lung, and Blood Institute

The discovery of the agent that causes AIDS prompted the NHLBI to assess and redirect previously supported activities and plans for future research. The Institute is now focusing its efforts on epidemiological studies of the natural history of the disease after exposure to blood products; evaluation of the tests, or assays, used to detect the agent in blood and blood products.

The latter category, the prevention of transfusion-related AIDS, is a new effort planned for 1985. Universal screening of blood products will certainly help prevent the transmission of AIDS through blood products. However, it is unlikely that any single test will identify every unit of blood with the HTLV-III virus. Development of methods to remove or inactivate the virus from blood products would provide extra assurance that the virus is not transmitted. A second initiative would develop and test in animals which immunoglobulin preparations are capable of protecting against AIDS; that is, which immunoglobulins have neutralizing activity against HTLV-III.

The Institute will continue to support several epidemiological studies. Among these is a study of blood product use and immune system changes in approximately 3,500 subjects and controls. This study takes advantage of the unique opportunity that now exists to collect and store blood specimens from a large number of donors before universal screening becomes possible. Samples will be tested for the HTLV-III virus; those found positive will be linked to the recipients that had received the blood products. These cohorts of recipients and donors of positive units will then be followed to determine the long term immunologic and clinical status. The Institute will also continue to develop a promising animal model that may prove exceedingly useful for studies of the transmission of AIDS, the progression of the disease, and the safety and efficacy of proposed interventions.

National Institute of Dental Research

Scientists at the NIDR are actively involved in the search to identify the basic mechanisms responsible for the profound immunosuppression that characterizes AIDS. These investigations have focused on the role of the monocyte in this disease, in contrast to other NIH laboratories, which have focused on T and B lymphocyte abnormalities. The NIDR has identified a number of monocyte abnormalities, including depression of killing function, chemotactic activity, mediator production, and follow-up microbicidal product release. In preliminary studies, investigators are beginning to extend these observations to an examination of monocyte surface receptor activity and inhibitor production. The oral cavity is often the site of presentation and incapacitating complications in AIDS as a result of mucocutaneous candidiasis, herpes simplex virus, and Kaposi's sarcoma.

The continuation and expansion of these studies made possible by the House allowance are extremely important for several reasons. First, the monocyte is the first line of host defense against a variety of antigens, bacteria, viruses, and protozoan parasites. Second, the monocyte presents antigen to T lymphocytes and generates a variety of inflammatory mediators that initiate, augment, and integrate inflammatory responses. Third, characterization of the immunosuppression is crucial to identification of immunomodulatory agents that can be used clinically to enhance or augment the depressed immune responses in patients with AIDS.

National Institute of Neurological and Communicative Disorders and Stroke

In FY 1985, the NINCDS will continue clinical studies of AIDS patients with evidence of a neurological disorder as well as patients who have AIDS but no evidence of brain involvement. In these studies, cerebral spinal fluid and brain tissues from the patients will be tested for the presence of retroviruses as well as an attempt to develop diagnostic tests for AIDS. Serum specimens that have been tested for opportunistic infections will be examined for retrovirus antibodies. Electron microscopic studies of central nervous tissue for retrovirus will largely supplant attempts to isolate the virus, but the possibility that viruses other than HTLV-III could cause or contribute to AIDS will also be considered. Collaborative studies with NCI attempting to produce AIDS in primates have demonstrated hematological changes transmitted by passage of infectious materials. Since these early experiments have been successful, experimental diagnostic and therapeutic procedures are being initiated.

In other studies, the NINCDS will test human sera with Simian Acquired Immune Deficiency Syndrome (SAIDS) agent for evidence of antibodies. Tissue from monkeys infected with SAIDS and other opportunistic infections (simian virus-40, toxoplasmosis, and measles) will continue to be studied with electron microscopy. Scientists will conduct comparative immunological characterization of SAIDS and AIDS. Monkeys with SAIDS will be treated with interleukin-2 in attempts to enhance their susceptibility to AIDS infection. The experience of developing a vaccine for SAIDS may help to test procedures for the development of an AIDS vaccine. NINCDS investigators will apply retrovirus probes in attempts to identify the AIDS virus in the nervous system.

National Institute of Allergy and Infectious Diseases

In 1985 the NIAID will intensify its efforts in such areas as the natural history of the disease, development of animal models and vaccines for HTLV-III, and the development and testing of chemotherapeutic agents for HTLV-III and the resultant opportunistic infections.

Specifically, 5,000 homosexual men residing in Baltimore, Berkeley, Chicago, Los Angeles, and Pittsburgh are being followed longitudinally for 3 years. Funds will be diverted from some activities described in the House report language in order to undertake new efforts to resolve issues concerning the clinical spectrum of HTLV-III infections, the implications of a positive serologic test for an individual, the prevalence of circulating and/or shed virus in antibody-positive persons, and the prognosis for seropositive individuals with mild or no signs of the disease. Biological specimens will be collected and frozen; these will then be made available to intramural and extramural scientists for evaluation.

In an attempt to learn about the pathology of retrovirus infections and for testing possible vaccines and antiviral drugs for HTLV-III, the NIAID has scheduled a meeting on "Animal Models of Retrovirus Infection" for November 1984. Several possible animal retrovirus systems that might serve as models for evaluation of problems associated with HTLV-III vaccine development will be discussed. Full development of these systems will require extensive *in vitro* and *in vivo* testing of the most likely candidates. In addition, NIAID intramural scientists are attempting to develop a recombinant HTLV-III vaccine using the vaccinia vector system (VVS). The VVS, developed by NIAID, has recently been used to develop a vaccine for hepatitis and shown promise in animal studies. Application of this new technique to the development of an AIDS vaccine represents a novel and potentially promising approach.

Prior to and even with the development of an effective vaccine, some patients will continue to develop AIDS and the opportunistic infections associated with the syndrome. Consequently, studies of the basic biology of these infections will be continued. Particular attention will be directed toward the development of new or improved therapy of candidiasis, cryptosporidiosis, cytomegalovirus, Mycobacterium avium-intracellulare and Pneumocystis carinii infections. NIAID will develop a mechanism to coordinate testing of therapeutic agents found in these studies.

An outreach program has been established to transmit the latest technical advances in AIDS research to primary care physicians and allied health personnel. These activities will also be continued in FY 1985.

National Eye Institute

Patients with AIDS are susceptible to a variety of ocular infections including one of the herpesviruses, cytomegalovirus (CMV) retinitis, a serious inflammation of the light-sensitive tissue that lines the inside of the back of the eye. Investigators have found that patients with CMV retinitis are at high risk of dying within a few months, apparently because their immune systems have been drastically impaired by the time the eye infections occur. In severe cases, blindness may precede death, thereby adding to the spectrum of suffering for AIDS victims. For these reasons, NEI staff opthalmologists will continue to perform eye examinations on AIDS patients at the NIH Clinical Center in consultation with staff of other Institutes as part of their clinical workups of these patients. New projects planned for 1985 include an epidemiological study of the various forms of retinitis that can occur in a population at risk from AIDS. In another east coast study, investigators will attempt to determine why so many AIDS patients in that population have ocular herpes zoster infections. The results of blood immunological assays will be analyzed to make this determination. As in other diseases, the monitoring of the development of AIDS in the eye may provide a sensitive index of systemic disease progression and of the effectiveness of experimental therapies.

Division of Research Resources

The DRR will continue its research efforts in 1985 in the area of AIDS, SAIDS, and AIDS/SAIDS-related research activities. Clinical studies of AIDS will continue to be conducted within the General Clinical Research Centers. In several of these centers, treatment modalities of patients with AIDS, including bone marrow implantation, are being tested. It is anticipated that these studies will facilitate the development of new treatment methodologies.

Outbreaks of spontaneously occurring SAIDS have occurred in nonhuman primates at four of the seven DRR-supported Regional Primate Researh Centers. The epidemiologic, pathologic, immunologic, and virologic features of this disease show many similarities to those seen in human AIDS patients, thus making SAIDS potentially a very good model system for basic studies on human AIDS. There is a high mortality rate in nonhuman primates affected by SAIDS, and this disease represents a threat to the health status of thousands of research animals in these Centers.

Studies to date indicate that type D retroviruses are the causative agents of SAIDS at all four Centers. The disease has been experimentally transmitted to normal nonhuman primates at the California Center by inoculating them with the type D retrovirus isolated from SAIDS-affected animals. These retroviruses which appear to cause SAIDS are not the same retrovirus which has been reported to be the probable causative agent of human AIDS.

Studies on SAIDS at the four Regional Primate Research Centers are continuing. The retroviruses which have been isolated at the four Centers will be further characterized by extensive biochemical and immunological studies. In addition, attempts will be initiated to develop an antiserum to permit rapid and reliable field detection of SAIDS and SAIDS-carriers in the Centers' primate colonies. As soon as adequate laboratory characterization of the SAIDS retroviruses are completed, attempts will be made to develop vaccines to immunize nonhuman primates against the disease.

National Institutes of Health

FUNDING FOR RESEARCH ON ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

(dollars in thousands)

	1982 Actual	1983 Actual	1984 Estimate Approp.	1984 Estimate Suppl.	1984 Estimate Total	1985 Approp.
NCI	$2,400	$9,790	$14,588	$2,000	$16,588	$26,851
NHLBI	5	1,202	4,890	---	4,890	8,459
NIDR	25	25	30	---	30	411
NINCDS	31	684	1,547	---	1,547	1,150
NIAID	297	9,223	14,918	4,150	19,068	23,262
NEI	33	45	58	---	58	300
DRR	564	699	775	400	1,175	1,731
Total ...	3,355	21,668	36,806	6,550	43,356	62,164

SECTION 5: NIH AIDS Projects Funded in Fiscal Years 1983 and 1984

NIH AIDS PROJECTS FOR FISCAL YEARS 1983-84 BY INSTITUTE

National Institute of Allergy and Infectious Diseases (NIAID)

GRANT NUMBER PI NAME	START DATE	FY	DOLLARS AWARDED	PERCENT TO AIDS	DOLLARS FOR AIDS	GRANTEE INSTITUTION TITLE OF PROJECT
1 F32 AI07216-01 HOFFLIN, JESSE M	03-31-85	84	20,040	100	20,040	PALO ALTO MEDICAL FOUNDATION RES INST TOXOPLASMIC ENCEPHALITIS IN THE IMMUNOSUPPRESSED HOST
2 P01 AI12192-09 STAMM, WALTER E	07-01-78	83	827,358	13	107,557	UNIVERSITY OF WASHINGTON STD RESEARCH PROGRAM PROJECT
5 P01 AI12192-10 STAMM, WALTER E	07-01-78	84	869,675	13	113,058	UNIVERSITY OF WASHINGTON STD RESEARCH PROGRAM PROJECT
3 P01 AI12192-10S1 STAMM, WALTER E	07-01-78	84	108,696	13	14,130	UNIVERSITY OF WASHINGTON STD RESEARCH PROGRAM PROJECT AI-12192
2 P01 AI15036-06 SPARLING, PHILIP F	07-01-78	83	424,463	14	59,425	UNIVERSITY OF NORTH CAROLINA CHAPEL HILL NORTH CAROL PROGRAM ON SEXUALLY TRANSMITTED DISEASE
5 P01 AI15036-07 SPARLING, PHILIP F	07-01-78	84	463,325	14	64,866	UNIVERSITY OF NORTH CAROLINA CHAPEL HILL NORTH CAROLINA PROGRAM OF SEXUALLY TRANSMITTED DISEASE
2 P50 AI15321-06 BELLANTI, JOSEPH A	09-01-78	83	110,252	100	110,252	GEORGETOWN UNIVERSITY INTERDISCIPLINARY RESEARCH ON IMMUNOLOGIC DISEASES
5 P50 AI15321-07 BELLANTI, JOSEPH A	09-01-78	84	117,814	100	117,814	GEORGETOWN UNIVERSITY INTERDISCIPLINARY RESEARCH ON IMMUNOLOGIC DISEASES
3 P50 AI15321-07S1 BELLANTI, JOSEPH A	09-01-78	84	23,295	100	23,295	GEORGETOWN UNIVERSITY CENTERS FOR INTERDISCIPLINARY RESEARCH ON IMMUNOLOGIC DI
2 P50 AI15332-06 FAHEY, JOHN L	09-01-78	83	432,218	33	142,632	UNIVERSITY OF CALIFORNIA LOS ANGELES INTERDISCIPLINARY RESEARCH ON IMMUNOLOGIC DISEASE
3 P50 AI15332-06S1 FAHEY, JOHN L	09-01-78	83	76,153	33	25,130	UNIVERSITY OF CALIFORNIA LOS ANGELES ASSESSING & MEETING PSYCHOSOCIAL NEEDS OF AIDS PATIENTS
3 P50 AI15332-06S2 FAHEY, JOHN L	09-01-78	83	170,974	33	56,421	UNIVERSITY OF CALIFORNIA LOS ANGELES EFFECTIVE MANAGEMENT OF THE AIDS CRISIS BY PRIMARY CARE
3 P50 AI15332-06S3 FAHEY, JOHN L	09-01-78	83	54,745	33	18,066	UNIVERSITY OF CALIFORNIA LOS ANGELES INTERDISCIPLINARY RESEARCH ON IMMUNOLOGIC DISEASE
5 P50 AI15332-07 FAHEY, JOHN L	09-01-78	84	762,756	33	251,709	UNIVERSITY OF CALIFORNIA LOS ANGELES INTERDISCIPLINARY RESEARCH ON IMMUNOLOGIC DISEASE
2 R01 AI16212-04A1 RINALDO, CHARLES R, JR	09-01-79	83	118,393	100	118,393	UNIVERSITY OF PITTSBURGH CELL MEDIATED IMMUNITY DURING CYTOMEGALOVIRUS INFECTION
5 R01 AI16212-05 RINALDO, CHARLES R, JR	09-01-79	84	116,091	100	116,091	UNIVERSITY OF PITTSBURGH CELL MEDIATED IMMUNITY DURING CYTOMEGALOVIRUS INFECTION

PROGRAM #N143; SOURCE: OPEN/PEND FILE & AIDS FILE

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NIH AIDS PROJECTS FOR FISCAL YEARS 1983-84 BY INSTITUTE

GRANT NUMBER PI NAME	START DATE	FY	DOLLARS AWARDED	PERCENT TO AIDS	DOLLARS FOR AIDS	GRANTEE INSTITUTION TITLE OF PROJECT
5 R01 AI19772-02 PESANTI, EDWARD L	08-01-82	83	72,009	100	72,009	UNIVERSITY OF CONNECTICUT HEALTH CENTER PNEUMOCYSTIS CARINII: METABOLISM AND HOST DEFENSES
1 R13 AI20166-01 HOLMES, KING K	08-01-83	83	7,500	100	7,500	UNIVERSITY OF WASHINGTON FIFTH MEETING - INTERNATIONAL SOCIETY FOR STD RESEARCH
1 R01 AI20573-01 GARDNER, MURRAY B	09-15-83	83	124,253	100	124,253	UNIVERSITY OF CALIFORNIA DAVIS SIMIAN ACQUIRED IMMUNODEFICIENCY SYNDROME
5 R01 AI20573-02 GARDNER, MURRAY B	09-15-83	84	139,472	100	139,472	UNIVERSITY OF CALIFORNIA DAVIS SIMIAN ACQUIRED IMMUNODEFICIENCY SYNDROME
1 U01 AI20671-01 RUBINSTEIN, ARYE	05-01-83	83	392,745	100	392,745	YESHIVA UNIVERSITY PATHOGENESIS & EPIDEMIOLOGY OF ACQUIRED IMMUNODEFICIENCY
5 U01 AI20671-02 RUBINSTEIN, ARYE	05-01-83	84	672,542	100	672,542	YESHIVA UNIVERSITY PATHOGENESIS & EPIDEMIOLOGY OF ACQUIRED IMMUNODEFICIENCY
1 U01 AI20672-01 FAHEY, JOHN L	05-01-83	83	273,954	100	273,954	UNIVERSITY OF CALIFORNIA LOS ANGELES STUDIES OF ACQUIRED IMMUNO DEFICIENCY SYNDROME
3 U01 AI20672-01S1 FAHEY, JOHN L	05-01-83	83	78,133	100	78,133	UNIVERSITY OF CALIFORNIA LOS ANGELES CLINICAL & THERAPEUTIC STUDIES IN KS & RELATED AIDS
3 U01 AI20672-01S2 FAHEY, JOHN L	05-01-83	83	76,119	100	76,119	UNIVERSITY OF CALIFORNIA LOS ANGELES SIGNIFICANCE OF TH SUBPOPULATION REDUCTIONS IN AIDS
5 U01 AI20672-02 FAHEY, JOHN L	05-01-83	84	491,012	100	491,012	UNIVERSITY OF CALIFORNIA LOS ANGELES STUDIES OF ACQUIRED IMMUNO DEFICIENCY SYNDROME
1 U01 AI20673-01 HUGHES, WALTER T	04-01-83	83	86,505	100	86,505	ST. JUDE CHILDREN'S RESEARCH HOSPITAL DEVELOPMENTAL THERAPEUTICS FOR P CARINII PNEUMONITIS
5 U01 AI20673-02 HUGHES, WALTER T	04-01-83	84	91,355	100	91,355	ST. JUDE CHILDREN'S RESEARCH HOSPITAL DEVELOPMENTAL THERAPEUTICS FOR P CARINII PNEUMONITIS
1 U01 AI20674-01 MA, PEARL	04-01-83	83	116,974	100	116,974	ST. VINCENT'S HOSP & MED CTR NEW YORK PREVALENCE AND PATHOGENESIS OF CRYPTOSPORDIOSIS
5 U01 AI20674-02 MA, PEARL	04-01-83	84	143,695	100	143,695	ST. VINCENT'S HOSP & MED CTR NEW YORK PREVALENCE AND PATHOGENESIS OF CRYTOSPORDIOSIS
1 R01 AI20698-01 CHESS, LEONARD	09-15-83	83	161,991	100	161,991	COLUMBIA UNIVERSITY NEW YORK IMMUNOBIOLOGY OF THE ACQUIRED IMMUNODEFICIENCY SYNDROME
5 R01 AI20698-02 CHESS, LEONARD	09-15-83	84	167,150	100	167,150	COLUMBIA UNIVERSITY NEW YORK IMMUNOBIOLOGY OF THE ACQUIRED IMMUNODEFICIENCY SYNDROME

PROGRAM #N143; SOURCE: OPEN/PEND FILE & AIDS FILE

NIH AIDS PROJECTS FOR FISCAL YEARS 1983-84 BY INSTITUTE

GRANT NUMBER PI NAME	START DATE	FY	DOLLARS AWARDED	PERCENT TO AIDS	DOLLARS FOR AIDS	GRANTEE INSTITUTION TITLE OF PROJECT
1 R01 AI20717-01 GUPTA, SUDHIR	09-15-83	83	102,198	100	102,198	UNIVERSITY OF CALIFORNIA IRVINE AMLR AND LYMPHOID DIFFERENTIATION IN AIDS
5 R01 AI20717-02 GUPTA, SUDHIR	09-15-83	84	110,217	100	110,217	UNIVERSITY OF CALIFORNIA IRVINE AMLR AND LYMPHOID DIFFERENTIATION IN AIDS
1 R01 AI20729-01 LETVIN, NORMAN L	09-15-83	83	79,444	100	79,444	HARVARD UNIVERSITY IMMUNOREGULATION IN AIDS
5 R01 AI20729-02 LETVIN, NORMAN L	09-15-83	84	87,083	100	87,083	HARVARD UNIVERSITY IMMUNOREGULATION IN AIDS
1 R01 AI20731-01 MONTE-WICHER, VICTORIA	09-15-83	83	47,446	100	47,446	NEW YORK STATE DEPARTMENT OF HEALTH SEMEN--INDUCED IMMUNOSUPPRESSION
5 R01 AI20731-02 MONTE-WICHER, VICTORIA	09-15-83	84	50,818	100	50,818	NEW YORK STATE DEPARTMENT OF HEALTH SEMEN--INDUCED IMMUNOSUPPRESSION
1 R01 AI20736-01 PARKS, WADE P	09-30-83	83	292,916	100	292,916	UNIVERSITY OF MIAMI ACQUIRED IMMUNODEFICIENCY DISEASE IN HAITIAN CHILDREN
5 R01 AI20736-02 PARKS, WADE P	09-30-83	84	293,668	100	293,668	UNIVERSITY OF MIAMI ACQUIRED IMMUNODEFICIENCY DISEASE IN HAITIAN CHILDREN
1 R01 AI20911-01A1 MILLER, GERALDINE P	09-30-84	84	77,193	100	77,193	UNIVERSITY OF TEXAS HLTH SCI CTR HOUSTON HUMAN IN VITRO RESPONSES TO CRYPTOCOCCUS NEOFORMANS
1 R01 AI20940-01 IVEY, MICHAEL H	04-01-84	84	98,892	100	98,892	UNIVERSITY OF OKLAHOMA HLTH SCIENCES CTR ASSAY FOR PNEUMOCYSTOSIS IN IMMUNODEFICIENT HOSTS
1 U01 AI21105-01 HORWITZ, MARSHALL S	04-01-84	84	118,103	100	118,103	YESHIVA UNIVERSITY ADENOVIRUSES AS A COFACTOR AND IMMUNE MODULATOR IN AIDS
1 U01 AI21118-01 TATTERSALL, PETER J	03-01-84	84	161,339	100	161,339	YALE UNIVERSITY ASSESSMENT OF A POSSIBLE PARVOVIRAL ETIOLOGY FOR AIDS
1 U01 AI21122-01 PARKS, WADE P	02-01-84	84	159,534	100	159,534	UNIVERSITY OF MIAMI HTLV RETROVIRUS INFECTION IN HAITIANS WITH AIDS
1 U01 AI21129-01 MULDER, CAREL	02-01-84	84	88,101	100	88,101	UNIVERSITY OF MASSACHUSETTS MEDICAL SCH MOLECULAR BIOLOGICAL STUDIES ON THE ETIOLOGY OF AIDS
1 U01 AI21134-01 PREBLE, OLIVIA T	05-01-84	84	51,025	100	51,025	U.S. UNIFORMED SERVICES UNIV OF HLTH SCI INFECTIOUS ETIOLOGY OF AIDS IN HEMOPHILIACS
1 U01 AI21141-01 ANDERSON, DEBORAH J	04-01-84	84	70,324	100	70,324	DANA-FARBER CANCER INSTITUTE ROLE OF SEMEN IN ACQUIRED IMMUNODEFICIENCY SYNDROME

PROGRAM #N143; SOURCE: OPEN/PEND FILE & AIDS FILE

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NIH AIDS PROJECTS FOR FISCAL YEARS 1983-84 BY INSTITUTE

GRANT NUMBER PI NAME	START DATE	FY	DOLLARS AWARDED	PERCENT TO AIDS	DOLLARS FOR AIDS	GRANTEE INSTITUTION TITLE OF PROJECT
1 R01 AI21161-01 SULLIVAN, JOHN L	09-15-83	83	177,810	100	177,810	UNIVERSITY OF MASSACHUSETTS MEDICAL SCH IMMUNOREGULATORY DEFECTS IN HEMOPHILIA
5 R01 AI21161-02 SULLIVAN, JOHN L	09-15-83	84	192,713	100	192,713	UNIVERSITY OF MASSACHUSETTS MEDICAL SCH IMMUNOREGULATORY DEFECTS IN HEMOPHILIA
1 U01 AI21175-01 LANGE, MICHAEL	09-30-83	83	304,989	100	304,989	ST. LUKE'S-ROOSEVELT INST FOR HLTH SCI PROSPECTIVE STUDY OF IMMUNOLOGIC ABNORMALITIES
3 U01 AI21175-01S1 LANGE, MICHAEL	09-30-83	84	34,300	100	34,300	ST. LUKE'S-ROOSEVELT INST FOR HLTH SCI PROSPECTIVE STUDY OF IMMUNOLOGIC ABNORMALITIES
5 U01 AI21175-02 LANGE, MICHAEL	09-30-83	84	336,937	100	336,937	ST. LUKE'S-ROOSEVELT INST FOR HLTH SCI PROSPECTIVE STUDY OF IMMUNOLOGIC ABNORMALITIES
1 U01 AI21182-01 SIDDIQUI, ALEEM	04-01-84	84	78,985	100	78,985	UNIVERSITY OF COLORADO HLTH SCIENCES CTR HEPATITIS B VIRUS AS COCARCINOGEN IN KAPOSI SARCOMA
1 U01 AI21186-01 MILLER, I GEORGE, JR	02-01-84	84	188,495	100	188,495	YALE UNIVERSITY RETROVIRUSES AND OTHER VIRAL COFACTORS IN AIDS
1 U01 AI21189-01 CHAGANTI, RAJU S	02-01-84	84	105,535	100	105,535	SLOAN-KETTERING INSTITUTE FOR CANCER RES CYTOGENETIFCS OF LYMPHOID PROLIFERATION IN AIDS PATIENTS
1 R43 AI21209-01 WIDDER, KENNETH J	07-01-84	84	42,286	100	42,286	MOLECULAR BIOSYSTEMS, INC. POSSIBLE AIDS DIAGNOSTIC TEST
1 P01 AI21289-01 RICH, ROBERT R	09-30-84	84	246,750	50	123,375	BAYLOR COLLEGE OF MEDICINE REGULATORY ABNORMALITIES IN IMMUNOLOGIC DISEASES
1 R01 AI21510-01 MURRAY, HENRY W	07-01-84	84	168,470	100	168,470	CORNELL UNIVERSITY MEDICAL CENTER ROLE & EFFECT OF GAMMA INTERFERON IN THE AIDS SYNDROME
1 R01 AI21516-01 BARTLETT, JOHN G	06-01-84	84	228,632	100	228,632	JOHNS HOPKINS UNIVERSITY ENTERIC DISEASES IN A POPULATION AT RISK FOR AIDS
1 R01 AI21874-01 MC CARTHY, CHARLOTTE M	09-30-84	84	79,054	100	79,054	NEW MEXICO STATE UNIVERSITY LAS CRUCES ASSESSMENT OF DRUG RESISTANCE IN MYCOBACTERIUM AVIUM
1 R01 AI21897-01 GANGADHARAM, PATTISAPU R	09-30-84	84	107,846	100	107,846	NATIONAL JEWISH HOSP & RES CTR-NAT'L AST IMMUNOPATHOLOGY OF MYCOBACTERIUM INTRACELLULARE IN AIDS
1 R01 AI21917-01 MURRAY, HENRY W	09-30-84	84	109,837	100	109,837	CORNELL UNIVERSITY MEDICAL CENTER GAMMA INTERFERON--MYCOBACTERIUM AVIUM INFECTION IN AIDS
1 R01 AI21919-01 CROWLE, ALFRED J	09-30-84	84	91,541	100	91,541	UNIVERSITY OF COLORADO HLTH SCIENCES CTR MECHANISMS OF M AVIUM INFECTION IN AIDS

ROGRAM #N143; SOURCE: OPEN/PEND FILE & AIDS FILE

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NIH AIDS PROJECTS FOR FISCAL YEARS 1983-84 BY INSTITUTE

GRANT NUMBER PI NAME	START DATE	FY	DOLLARS AWARDED	PERCENT TO AIDS	DOLLARS FOR AIDS	GRANTEE INSTITUTION TITLE OF PROJECT
1 R01 AI21929-01 IMAEDA, TAMOTSU	09-30-84	84	71,792	100	71,792	UNIVERSITY OF MEDICINE & DENTISTRY OF NJ MYCOBACTERIM AVIUM INTRACELLULARE IN AIDS PATIENTS
1 R01 AI21931-01 GANZ, TOMAS	09-30-84	84	111,604	100	111,604	UNIVERSITY OF CALIFORNIA LOS ANGELES MICROBICIDAL MECHANISMS AGAINST PNEUMOCYSTIS CARINII
1 R01 AI21938-01 ARMSTRONG, DONALD	09-30-84	84	38,395	100	38,395	MEMORIAL HOSPITAL FOR CANCER & ALLIED DI PENTAMIDINE PHARMACOKINETICS IN ANIMALS AND HUMANS
1 R01 AI21946-01 BARROW, WILLIAM W	09-30-84	84	41,240	100	41,240	TEXAS COLLEGE OF OSTEOPATHIC MEDICINE PROCESSING OF MYCOBACTERIAL GLYCOPEPTIDOLIPID ANTIGENS
1 R01 AI21947-01 LEHMANN, PAUL F	09-30-84	84	61,356	100	61,356	MEDICAL COLLEGE OF OHIO AT TOLEDO MANNOPROTEIN BIOSYNTHESIS AND ITS ROLE IN PATHOGENICITY
1 R01 AI21951-01 LIPSCOMB, MARY F	09-30-84	84	178,870	100	178,870	UNIVERSITY OF TEXAS HLTH SCI CTR DALLAS PULMONARY DEFENSES IN OPPORTUNISTIC INFECTIONS
1 R01 AI21953-01 MILLER, RICHARD A	09-30-84	84	81,518	100	81,518	UNIVERSITY OF WASHINGTON HUMORAL IMMUNITY TO CRYPTOSPORIDIUM IN PRIMATES
1 N01 AI32503-00 CICMANEC, JOHN L	05-19-83	83	169,078	100	169,078	MELOY LABORATORIES HOUSING ANIMALS FOR STUDIES OF INFECTIOUS DISEASES
5 N01 AI32503-01 CICMANEC, JOHN L	05-19-83	84	117,649	100	117,649	MELOY LABORATORIES HOUSING ANIMALS FOR STUDIES OF INFECTIOUS DISEASES
1 N01 AI32507-00 BAKER, LOUIS N	07-22-83	83	550,838	100	550,838	NEW YORK BLOOD CENTER COLLECT SPECIMENS TO DETECT ETIOLOGIC AGENTS OF AIDS
5 N01 AI32507-05 BAKER, LOUIS N	07-22-83	84	578,322	100	578,322	NEW YORK BLOOD CENTER COLLECT SPECIMENS TO DETECT ETIOLOGIC AGENTS OF AIDS
5 N01 AI32507-06 BAKER, LOUIS N	07-22-83	84	201,697	100	201,697	NEW YORK BLOOD CENTER COLLECT SPECIMENS TO DETECT ETIOLOGIC AGENTS OF AIDS
1 N01 AI32511-00 DETELS, ROGER	09-30-83	83	669,165	100	669,165	UNIVERSITY OF CALIFORNIA LOS ANGELES NATURAL HISTORY OF ACQUIRED IMMUNE DEFICIENCY SYNDROME
5 N01 AI32511-03 DETELS, ROGER	09-30-83	84	544,861	100	544,861	UNIVERSITY OF CALIFORNIA LOS ANGELES NATURAL HISTORY OF ACQUIRED IMMUNE DEFICIENCY SYNDROME
5 N01 AI32511-06 DETELS, ROGER	09-30-83	84	629,025	100	629,025	UNIVERSITY OF CALIFORNIA LOS ANGELES NATURAL HISTORY OF ACQUIRED IMMUNE DEFICIENCY SYNDROME
1 N01 AI32513-00 RINALDO, CHARLES R, JR	09-30-83	83	782,790	100	782,790	UNIVERSITY OF PITTSBURGH NATURAL HISTORY OF ACQUIRED IMMUNE DEFICIENCY SYNDROME

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5 N01 AI32513-01 RINALDO, CHARLES R, JR	09-30-83	83	156,000	100	156,000	UNIVERSITY OF PITTSBURGH NATURAL HISTORY OF ACQUIRED IMMUNE DEFICIENCY SYNDROME
5 N01 AI32513-04 RINALDO, CHARLES R, JR	09-30-83	84	1,109,920	100	1,109,920	UNIVERSITY OF PITTSBURGH NATURAL HISTORY OF ACQUIRED IMMUNE DEFICIENCY SYNDROME
5 N01 AI32513-06 RINALDO, CHARLES R, JR	09-30-83	84	665,311	100	665,311	UNIVERSITY OF PITTSBURGH NATURAL HISTORY OF ACQUIRED IMMUNE DEFICIENCY SYNDROME
1 N01 AI32519-00 WINKELSTEIN, WARREN, JR	09-30-83	83	676,951	100	676,951	UNIVERSITY OF CALIFORNIA BERKELEY NATURAL HISTORY OF ACQUIRED IMMUNE DEFICIENCY SYNDROME
5 N01 AI32519-04 WINKELSTEIN, WARREN, JR	09-30-83	84	615,627	100	615,627	UNIVERSITY OF CALIFORNIA BERKELEY NATURAL HISTORY OF ACQUIRED IMMUNE DEFICIENCY SYNDROME
3 N01 AI32519-05 WINKELSTEIN, WARREN, JR	09-30-83	84	443,285	100	443,285	UNIVERSITY OF CALIFORNIA BERKELEY NATURAL HISTORY OF ACQUIRED IMMUNE DEFICIENCY SYNDROME
1 N01 AI32520-00 POLK, B FRANK	09-30-83	83	471,663	100	471,663	JOHNS HOPKINS UNIVERSITY NATURAL HISTORY OF ACQUIRED IMMUNE DEFICIENCY SYNDROME
5 N01 AI32520-01 POLK, B FRANK	09-30-83	83	94,000	100	94,000	JOHNS HOPKINS UNIVERSITY NATURAL HISTORY OF ACQUIRED IMMUNE DEFICIENCY SYNDROME
5 N01 AI32520-04 POLK, B FRANK	09-30-83	84	404,269	100	404,269	JOHNS HOPKINS UNIVERSITY NATURAL HISTORY OF ACQUIRED IMMUNE DEFICIENCY SYNDROME
3 N01 AI32520-05 POLK, B FRANK	09-30-83	84	517,879	100	517,879	JOHNS HOPKINS UNIVERSITY NATURAL HISTORY OF ACQUIRED IMMUNE DEFICIENCY SYNDROME
1 Y01 AI40012-00 KASLOW, RICHARD A	08-07-84	84	33,940	100	33,940	U.S. NATIONAL INSTITUTES OF HLTH MENTAL HEALTH EFFECTS OF AIDS ON AT-RISK HOMOSEXUAL MEN
1 N01 AI42543-00 SMITH, JAMES H	07-10-84	84	149,225	100	149,225	INDIANA UNIV-PURDUE UNIV AT INDIANAPOLIS DEVELOP DRUGS FOR TREATMENT OF PNEUMOCYSTIC CARINII
1 N01 AI42544-00 ISEMAN, MICHAEL D	07-23-84	84	227,559	100	227,559	NATIONAL JEWISH HOSP & RES CTR-NAT'L AST DRUG TREATMENT OF M. AVIUM-INTRACELLULARE IN AIDS
1 N01 AI42545-00 YOUNG, LOWELL S	07-23-84	84	186,123	100	186,123	UNIVERSITY OF CALIFORNIA LOS ANGELES DRUG TREATMENT OF M. AVIUM-INTRACELLULARE IN AIDS
1 N01 AI42547-00 LOPEZ-BERESTEIN, GABRIEL	07-16-84	84	159,494	100	159,494	UNIVERSITY OF TEXAS SYSTEM CANCER CENTER DEVELOP DRUGS FOR TREATMENT OF CANDIDIASIS
1 N01 AI42548-00 WALZER, PETER D	07-10-84	84	160,024	100	160,024	UNIVERSITY OF CINCINNATI DEVELOP DRUGS FOR TREATMENT OF PNEUMOCYSTIC CARINII

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1 N01 AI42549-00 CLARK, ALICE M	07-23-84	84	144,836	100	144,836	UNIVERSITY OF MISSISSIPPI DEVELOP DRUGS FOR TREATMENT OF CANDIDIASIS
1 N01 AI42554-00 DRACH, JOHN C	08-01-84	84	671,023	100	671,023	UNIVERSITY OF MICHIGAN AT ANN ARBOR DEVELOP ANTIVIRAL DRUGS FOR CMV INFECTIONS IN AIDS
1 N01 AI42555-00 SHANNON, WILLIAM M	08-01-84	84	137,133	100	137,133	SOUTHERN RESEARCH INSTITUTE DEVELOP ANTIVIRAL DRUGS FOR CMV INFECTIONS IN AIDS
1 N01 AI42556-00 WRIGHT, GEORGE E	08-01-84	84	157,279	100	157,279	UNIVERSITY OF MASSACHUSETTS MEDICAL SCH DEVELOP ANTIVIRAL DRUGS FOR CMV INFECTIONS IN AIDS
1 N01 AI42557-00 ALBRECHT, THOMAS B	09-01-84	84	284,771	100	284,771	UNIVERSITY OF TEXAS MED BR GALVESTON DEVELOP ANTIVIRAL DRUGS FOR CMV INFECTIONS IN AIDS
1 N01 AI42651-00 BECKER, JEFFREY M	07-30-84	84	222,553	100	222,553	UNIVERSITY OF TENNESSEE KNOXVILLE DEVELOP DRUGS FOR TREATMENT OF CANDIDIASIS
	INSTITUTE TOTAL		24,691,203	102	21,230,459	

National Cancer Institute (NCI)

GRANT NUMBER PI NAME	START DATE	FY	DOLLARS AWARDED	PERCENT TO AIDS	DOLLARS FOR AIDS	GRANTEE INSTITUTION TITLE OF PROJECT
5 R01 CA19341-07 HASELTINE, WILLIAM A	06-01-79	83	117,855	10	11,786	DANA-FARBER CANCER INSTITUTE THE MOLECULAR BIOLOGY OF REPLICATION RNA TUMOR VIRUSES
5 R01 CA19341-08 HASELTINE, WILLIAM A	06-01-79	84	142,570	10	14,257	DANA-FARBER CANCER INSTITUTE THE MOLECULAR BIOLOGY OF REPLICATION RNA TUMOR VIRUSES
3 R01 CA33205-01S1 MARMOR, MICHAEL	09-30-82	83	16,350	100	16,350	NEW YORK UNIVERSITY RISK FACTORS FOR KAPOSI'S SARCOMA IN HOMOSEXUAL MEN
2 R01 CA33205-02 MARMOR, MICHAEL	09-30-82	84	251,794	100	251,794	NEW YORK UNIVERSITY RISK FACTORS FOR KAPOSI'S SARCOMA IN HOMOSEXUAL MEN
1 R01 CA33873-01A1 MERTELSMANN, ROLAND H	08-01-83	83	104,431	100	104,431	SLOAN-KETTERING INSTITUTE FOR CANCER RES INTERLEUKIN-2 IN HUMAN IMMUNODEFICIENCY SYNDROMES
5 R01 CA33873-02 MERTELSMANN, ROLAND H	08-01-83	84	110,788	100	110,788	SLOAN-KETTERING INSTITUTE FOR CANCER RES INTERLEUKIN-2 IN HUMAN IMMUNODEFICIENCY SYNDROMES
1 R23 CA34671-01 CIANCIOLO, GEORGE J	09-30-83	83	52,244	100	52,244	DUKE UNIVERSITY INHIBITORS OF MACROPHAGES IN NEOPLASIA RELATIONSHIP
5 R23 CA34671-02 CIANCIOLO, GEORGE J	09-30-83	84	53,720	100	53,720	DUKE UNIVERSITY INHIBITORS OF MACROPHAGES IN NEOPLASIA RELATIONSHIP
1 R01 CA34674-01 HERSH, EVAN M	02-07-83	83	184,958	100	184,958	UNIVERSITY OF TEXAS SYSTEM CANCER CENTER STUDY OF ACQUIRED IMMUNODEFICIENCY AND KAPOSI'S SARCOMA

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5 R01 CA34674-02 HERSH, EVAN M	02-07-83	84	198,741	100	198,741	UNIVERSITY OF TEXAS SYSTEM CANCER CENTER STUDY OF ACQUIRED IMMUNODEFICIENCY AND KAPOSI'S SARCOMA
1 R01 CA34729-01 SPECTOR, DEBORAH H	05-01-83	83	99,563	100	99,563	UNIVERSITY OF CALIFORNIA SAN DIEGO HUMAN CMV, CELL-RELATED DNA, ONCOGENES & KAPOSI SARCOMA
5 R01 CA34729-02 SPECTOR, DEBORAH H	05-01-83	84	115,844	100	115,844	UNIVERSITY OF CALIFORNIA SAN DIEGO HUMAN CMV, CELL-RELATED DNA, ONCOGENES & KAPOSI SARCOMA
1 R01 CA34822-01 SAFAI, BIJAN	09-30-83	83	190,939	100	190,939	MEMORIAL HOSPITAL FOR CANCER & ALLIED DI EPIDEMIOLOGY: KAPOSI SARCOMA-ACQUIRED IMMUNE DEFICIENCY
1 U01 CA34975-01 MULLINS, JAMES I	05-01-83	83	143,699	100	143,699	HARVARD UNIVERSITY MALIGNANCY ASSOCIATED GENETIC CHANGES--KAPOSI'S SARCOMA
5 U01 CA34975-02 MULLINS, JAMES I	05-01-83	84	126,262	100	126,262	HARVARD UNIVERSITY RETROVIRUSES AND AIDS
1 U01 CA34976-01 VALENTINE, FRED T	06-01-83	83	166,822	100	166,822	NEW YORK UNIVERSITY ETIOLOGY AND IMMUNOLOGICAL BASIS OF THE AID SYNDROME
5 U01 CA34976-02 VALENTINE, FRED T	06-01-83	84	171,305	100	171,305	NEW YORK UNIVERSITY ETIOLOGY AND IMMUNOLOGICAL BASIS OF THE AID SYNDROME
1 U01 CA34977-01 ANDES, W ABE	09-30-83	83	264,616	100	264,616	TULANE UNIVERSITY OF LOUISIANA A STUDY OF THE IMMUNODEFICIENCY IN HEMOPHILIA
5 U01 CA34977-02 ANDES, W ABE	09-30-83	84	261,892	100	261,892	TULANE UNIVERSITY OF LOUISIANA A STUDY OF THE IMMUNODEFICIENCY IN HEMOPHILIA
1 U01 CA34979-01 FINBERG, ROBERT W	09-30-83	83	60,631	100	60,631	DANA-FARBER CANCER INSTITUTE ANIMAL MODELS OF AIDS
5 U01 CA34979-02 FINBERG, ROBERT W	09-30-83	84	64,561	100	64,561	DANA-FARBER CANCER INSTITUTE ANIMAL MODELS OF AIDS
1 U01 CA34980-01 VOLBERDING, PAUL A	05-01-83	83	526,229	100	526,229	UNIVERSITY OF CALIFORNIA SAN FRANCISCO STUDIES OF ACQUIRED IMMUNE DEFICIENCY SYNDROME
3 U01 CA34980-01S2 VOLBERDING, PAUL A	05-01-83	83	48,526	100	48,526	UNIVERSITY OF CALIFORNIA SAN FRANCISCO STUDIES OF ACQUIRED IMMUNE DEFICIENCY SYNDROME
5 U01 CA34980-02 VOLBERDING, PAUL A	05-01-83	84	559,702	100	559,702	UNIVERSITY OF CALIFORNIA SAN FRANCISCO STUDIES OF ACQUIRED IMMUNE DEFICIENCY SYNDROME
1 U01 CA34981-01 HAUPTMAN, STEPHEN P	09-30-83	83	153,421	100	153,421	THOMAS JEFFERSON UNIVERSITY AIDS--MECHANISM OF DEFECTIVE IMMUNOREGULATION

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5 U01 CA34981-02 HAUPTMAN, STEPHEN P	09-30-83	84	152,570	100	152,570	THOMAS JEFFERSON UNIVERSITY AIDS--MECHANISM OF DEFECTIVE IMMUNOREGULATION
1 U01 CA34987-01 PIFER, LINDA L	09-30-83	83	24,737	100	24,737	UNIVERSITY OF TENN CENTER HEALTH SCIEN NONINVASIVE DIAGNOSIS OF PNEUMOCYSTIS IN AIDS PATIENTS
5 U01 CA34987-02 PIFER, LINDA L	09-30-83	84	92,620	100	92,620	UNIVERSITY OF TENN CENTER HEALTH SCIEN NONINVASIVE DIAGNOSIS OF PNEUMOCYSTIS IN AIDS PATIENTS
1 U01 CA34988-01 FISCHL, MARGARET A	09-30-83	83	134,029	100	134,029	UNIVERSITY OF MIAMI A STUDY OF AN ACQUIRED IMMUNODEFICIENCY SYNDROME
5 U01 CA34988-02 FISCHL, MARGARET A	09-30-83	84	169,224	100	169,224	UNIVERSITY OF MIAMI A STUDY OF AN ACQUIRED IMMUNODEFICIENCY SYNDROME
1 U01 CA34989-01 SIEGAL, FREDERICK P	05-01-83	83	254,011	100	254,011	MOUNT SINAI SCHOOL OF MEDICINE AIDS: CHARACTERIZATION OF EARLY DEFECTS
5 U01 CA34989-02 SIEGAL, FREDERICK P	05-01-83	84	330,121	100	330,121	MOUNT SINAI SCHOOL OF MEDICINE AIDS: CHARACTERIZATION OF EARLY DEFECTS
1 U01 CA34991-01 ZAIA, JOHN A	09-30-83	83	107,681	100	107,681	CITY OF HOPE NATIONAL MEDICAL CENTER ROLE OF CMV IN THE ACQUIRED IMMUNODEFICIENCY SYNDROME
5 U01 CA34991-02 ZAIA, JOHN A	09-30-83	84	112,662	100	112,662	CITY OF HOPE NATIONAL MEDICAL CENTER THE ROLE OF CMV IN THE ACQUIRED IMMUNODEFICIENCY SYNDROM
1 U01 CA34994-01 PREBLE, OLIVIA T	09-30-83	83	46,600	100	46,600	U.S. UNIFORMED SERVICES UNIV OF HLTH SCI INTERFERON AND THE ETIOLOGY OF ACQUIRED IMMUNODEFICIENCY
5 U01 CA34994-02 PREBLE, OLIVIA T	09-30-83	84	40,600	100	40,600	U.S. UNIFORMED SERVICES UNIV OF HLTH SCI INTERFERON AND THE ETIOLOGY OF ACQUIRED IMMUNODEFICIENCY
1 U01 CA34995-01 SAFAI, BIJAN	06-01-83	83	249,999	100	249,999	MEMORIAL HOSPITAL FOR CANCER & ALLIED DI PROSPECTIVE STUDY OF EPIDEMIC KAPOSI'S SARCOMA AND AIDS
5 U01 CA34995-02 SAFAI, BIJAN	06-01-83	84	266,397	100	266,397	MEMORIAL HOSPITAL FOR CANCER & ALLIED DI PROSPECTIVE STUDY OF EPIDEMIC KAPOSI'S SARCOMA AND AIDS
1 U01 CA35001-01 HUGHES, JOHN H	04-01-83	83	60,050	100	60,050	CHILDREN'S HOSPITAL (COLUMBUS) ASSESSMENT OF SEMINAL PLASMA & CMV INFECTIONS ON AIDS
5 U01 CA35001-02 HUGHES, JOHN H	04-01-83	84	87,614	100	87,614	CHILDREN'S HOSPITAL (COLUMBUS) ASSESSMENT OF SEMINAL PLASMA & CMV INFECTIONS ON AIDS
1 U01 CA35006-01 KIRKPATRICK, CHARLES H	09-30-83	83	172,538	100	172,538	NATIONAL JEWISH HOSP & RES CTR-NAT'L AST PATHOGENESIS OF ACQUIRED IMMUNE DEFICIENCY SYNDROME

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5 U01 CA35006-02 KIRKPATRICK, CHARLES H	09-30-83	84	184,583	100	184,583	NATIONAL JEWISH HOSP & RES CTR-NAT'L AST PATHOGENESIS OF ACQUIRED IMMUNE DEFICIENCY SYNDROME
1 U01 CA35018-01 DOUGLAS, R GORDON, JR	05-01-83	83	568,319	100	568,319	CORNELL UNIVERSITY MEDICAL CENTER COLLABORATIVE STUDIES OF AID/KAPOSI'S SARCOMA
3 U01 CA35018-01S1 DOUGLAS, R GORDON, JR	05-01-83	83	137,372	100	137,372	CORNELL UNIVERSITY MEDICAL CENTER COLLABORATIVE STUDIES OF AID/KAPOSI'S SARCOMA
5 U01 CA35018-02 DOUGLAS, R GORDON, JR	05-01-83	84	760,065	100	760,065	CORNELL UNIVERSITY MEDICAL CENTER COLLABORATIVE STUDIES OF AID/KAPOSI'S SARCOMA
1 U01 CA35020-01 HIRSCH, MARTIN S	05-01-83	83	124,335	100	124,335	MASSACHUSETTS GENERAL HOSPITAL VIRUSES ACQUIRED IMMUNODEFICIENCY AND KAPOSI SARCOMA
3 U01 CA35020-01S1 HIRSCH, MARTIN S	05-01-83	84	29,000	100	29,000	MASSACHUSETTS GENERAL HOSPITAL VIRUSES ACQUIRED IMMUNODEFICIENCY AND KAPOSI SARCOMA
5 U01 CA35020-02 HIRSCH, MARTIN S	05-01-83	84	123,310	100	123,310	MASSACHUSETTS GENERAL HOSPITAL VIRUSES ACQUIRED IMMUNODEFICIENCY AND KAPOSI SARCOMA
1 R13 CA35028-01 TOPP, WILLIAM C	01-07-83	83	20,367	100	20,367	COLD SPRING HARBOR LABORATORY WORKSHOP ON A I D SYNDROME AND KAPOSI'S SARCOMA
1 R01 CA35460-01A1 VOLSKY, DAVID J	03-15-84	84	83,465	10	8,347	UNIVERSITY OF NEBRASKA MEDICAL CENTER MONOCLONAL ANTI-EBNA ANTIBODIES
1 R01 CA35676-01 HOLLY, ELIZABETH A	09-30-83	83	95,303	100	95,303	NORTHERN CALIFORNIA CANCER PROGRAM, INC. EPIDEMIOLOGY: EWING'S SARCOMA, ANAL AND RECTAL CARCINOMA
5 R01 CA35676-02 HOLLY, ELIZABETH A	09-30-83	84	147,959	100	147,959	NORTHERN CALIFORNIA CANCER PROGRAM, INC. EPIDEMIOLOGY: EWING'S SARCOMA, ANAL AND RECTAL CARCINOM
1 R01 CA35683-01 HOLMES, FREDERICK F	09-30-83	83	58,453	100	58,453	UNIVERSITY OF KANSAS COL HLTH SCI & HOSP ANAL CANCER IN WOMEN: ETIOLOGIC FACTORS
5 R01 CA35683-02 HOLMES, FREDERICK F	09-30-83	84	92,344	100	92,344	UNIVERSITY OF KANSAS COL HLTH SCI & HOSP ANAL CANCER IN WOMEN: ETIOLOGIC FACTORS
1 R01 CA35706-01 PETERS, RUTH K	09-30-83	83	103,837	100	103,837	UNIVERSITY OF SOUTHERN CALIFORNIA EPIDEMIOLOGY OF EPITHELIAL TUMORS OF THE ANOGENITAL AREA
5 R01 CA35706-02 PETERS, RUTH K	09-30-83	84	118,029	100	118,029	UNIVERSITY OF SOUTHERN CALIFORNIA EPIDEMIOLOGY OF EPITHELIAL TUMORS OF THE ANOGENITAL AREA
9 R01 CA35922-04A1 SCHWARTZ, STANLEY A	09-30-83	83	66,747	100	66,747	UNIVERSITY OF MICHIGAN AT ANN ARBOR SUPPRESSOR CELLS IN CANCER AND IMMUNODEFICIENCIES

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5 R01 CA35922-05 SCHWARTZ, STANLEY A	09-30-83	84	65,371	100	65,371	UNIVERSITY OF MICHIGAN AT ANN ARBOR SUPPRESSOR CELLS IN CANCER AND IMMUNODEFICIENCIES
1 U01 CA35982-01 FRIEDMAN-KIEN, ALVIN E	07-15-83	83	395,000	100	395,000	NEW YORK UNIVERSITY EPIDEMIC KAPOSI'S SARCOMA
1 R01 CA36301-01A1 LEVINE, ALEXANDRA M	07-15-84	84	299,077	100	299,077	UNIVERSITY OF SOUTHERN CALIFORNIA EPIDEMIOLOGY & IMMUNOLOGY IN HOMOSEXUALS WITH PGL
9 R01 CA36642-04A1 CORLEY, RONALD B	09-30-83	83	123,117	100	123,117	DUKE UNIVERSITY HELPER T CELLS: COMPARISON OF T-T AND T-B INTERACTION
5 R01 CA36642-05 CORLEY, RONALD B	09-30-83	84	128,564	100	128,564	DUKE UNIVERSITY HELPER T CELLS: COMPARISON OF T-T AND T-B INTERACTION
1 R13 CA36751-01 SELIKOFF, IRVING J	09-30-83	83	10,000	100	10,000	NEW YORK ACADEMY OF SCIENCES CONFERENCE: ACQUIRED IMMUNE DEFICIENCY SYNDROME
3 R13 CA36751-01S1 SELIKOFF, IRVING J	09-30-83	84	25,000	100	25,000	NEW YORK ACADEMY OF SCIENCES CONFERENCE: ACQUIRED IMMUNE DEFICIENCY SYNDROME
1 U01 CA37259-01 ROSENTHAL, LEONARD J	04-01-84	84	145,662	100	145,662	GEORGETOWN UNIVERSITY ROLE OF HCMV IN KS ASSOCIATED WITH AIDS
1 U01 CA37265-01 MC DOUGALL, JAMES K	03-01-84	84	132,123	100	132,123	FRED HUTCHINSON CANCER RESEARCH CENTER CYTOMEGALOVIRUS IN AIDS AND KAPOSI'S SARCOMA
1 U01 CA37295-01 BASILICO, CLAUDIO	04-01-84	84	259,408	100	259,408	NEW YORK UNIVERSITY MOLECULAR BIOLOGY OF AIDS-RELATED TUMORS
1 U01 CA37314-01 HAYWARD, GARY S	04-01-84	84	114,987	100	114,987	JOHNS HOPKINS UNIVERSITY INTERACTION OF EBV AND CMV IN AIDS KAPOSI'S SARCOMA
1 U01 CA37327-01 GERMAN, JAMES L, III	03-01-84	84	76,372	100	76,372	NEW YORK BLOOD CENTER CHROMOSOME MUTATION IN THE PATHOGENESIS OF AIDS
1 R01 CA37437-01 CHOI, YONG S	09-30-83	83	107,422	100	107,422	SLOAN-KETTERING INSTITUTE FOR CANCER RES FUNCTIONAL ANALYSIS OF T-LYMPHOCYTE SUBPOPULATIONS
5 R01 CA37437-02 CHOI, YONG S	09-30-83	84	118,837	100	118,837	SLOAN-KETTERING INSTITUTE FOR CANCER RES FUNCTIONAL ANALYSIS OF T-LYMPHOCYTE SUBPOPULATIONS
1 U01 CA37461-01 SCHOOLEY, ROBERT T	04-01-84	84	100,313	100	100,313	MASSACHUSETTS GENERAL HOSPITAL HUMAN T-CELL LEUKEMIA VIRUS--VIRUS-HOST INTERACTIONS
1 U01 CA37465-01 VOLSKY, DAVID J	04-01-84	84	125,225	100	125,225	CREIGHTON UNIVERSITY STUDIES OF THE VIRAL ETIOLOGY OF AIDS

PROGRAM #N143; SOURCE: OPEN/PEND FILE & AIDS FILE

NIH AIDS PROJECTS FOR FISCAL YEARS 1983-84 BY INSTITUTE

• GRANT NUMBER PI NAME	START DATE	FY	DOLLARS AWARDED	PERCENT TO AIDS	DOLLARS FOR AIDS	GRANTEE INSTITUTION TITLE OF PROJECT
1 U01 CA37466-01 ESSEX, MYRON E	04-01-84	84	156,966	100	156,966	HARVARD UNIVERSITY ASSOCIATION BETWEEN HTLV AND AIDS
1 U01 CA37467-01 GARDNER, MURRAY B	03-01-84	84	171,558	100	171,558	UNIVERSITY OF CALIFORNIA DAVIS SIMIAN ACQUIRED IMMUNODEFICIENCY SYNDROME--A MODEL
1 U01 CA37477-01 SUMAYA, CIRO V	04-01-84	84	67,918	100	67,918	UNIVERSITY OF TEXAS HLTH SCI CTR SAN ANT EPSTEIN-BARR VIRUS AND CHROMOSOMAL ABERRATIONS IN AIDS
1 U01 CA37478-01 POIESZ, BERNARD J	04-01-84	84	163,159	100	163,159	UPSTATE MEDICAL CENTER ACQUIRED IMMUNODEFICIENCY SYNDROME/ASSOCIATION WITH HTLV
1 R43 CA38502-01 BALINT, JOSEPH P, JR	09-30-84	84	50,000	100	50,000	IMRE CORPORATION IMMUNOADSORPTION THERAPY FOR KAPOSI'S SARCOMA
	INSTITUTE TOTAL		12,038,483	78	11,728,983	
NCI - Div. of Cancer Biology and Diagnosis-						
3 N01 CB25005-01 WEATHERLY, BRIAN S	09-30-82	83	16,241	70	11,369	BIOQUAL, INC. FACILITY FOR VIRUS INFECTED AND CHIMERIC MICE
3 N01 CB25005-02 WEATHERLY, BRIAN S	09-30-82	83	250,409	70	175,286	BIOQUAL, INC. FACILITY FOR VIRUS INFECTED AND CHIMERIC MICE
3 N01 CB25005-04 WEATHERLY, BRIAN S	09-30-82	84	265,162	70	185,613	BIOQUAL, INC. FACILITY FOR VIRUS INFECTED AND CHIMERIC MICE
	INSTITUTE TOTAL		531,812	3	372,268	
NCI - Div. of Cancer Treatment						
5 N01 CM05724-15 SARNGADHARAN, M G	09-30-80	83	400,000	12	48,000	LITTON BIONETICS PROVIDE ANIMAL FACILITIES FOR VIRAL CANCER RESEARCH
3 N01 CM05724-17 SARNGADHARAN, M G	09-30-80	84	400,000	12	48,000	LITTON BIONETICS PROVIDE ANIMAL FACILITIES FOR VIRAL CANCER RESEARCH
5 N01 CM25608-01 SMITH, RICHARD G	09-30-82	83	293,501	20	58,700	HEM RESEARCH, INC. SUPPLY HUMAN TUMORS NUCLEIC ACIDS AND RETROVIRUSES
3 N01 CM25608-03 SMITH, RICHARD G	09-30-82	83	74,663	20	14,933	HEM RESEARCH, INC. SUPPLY HUMAN TUMORS NUCLEIC ACIDS AND RETROVIRUSES
5 N01 CM25616-02 SARNGADHARAN, M G	03-21-82	83	579,507	80	463,606	LITTON BIONETICS PROVIDE HEMATOPOIETIC CELL CULTURES
5 N01 CM25616-03 SARNGADHARAN, M G	03-21-82	84	579,507	80	463,606	LITTON BIONETICS PROVIDE HEMATOPOIETIC CELL CULTURES
	INSTITUTE TOTAL		2,327,178	6	1,096,845	

PROGRAM #N143; SOURCE: OPEN/PEND FILE & AIDS FILE

NIH AIDS PROJECTS FOR FISCAL YEARS 1983-84 BY INSTITUTE

NCI - Office of the Director

GRANT NUMBER PI NAME	START DATE	FY	DOLLARS AWARDED	PERCENT TO AIDS	DOLLARS FOR AIDS	GRANTEE INSTITUTION TITLE OF PROJECT
3 N01 CO23909-04 LIVHEMAN, JAMES L	09-09-82	83	7,444,087	1	74,441	LITTON BIONETICS RESEARCH AT THE NCI FREDERICK CANCER RESEARCH FACILITY
5 N01 CO23909-07 VANDE WOUDE, GEORGE F	09-09-82	84	7,623,593	1	76,236	LITTON BIONETICS RESEARCH AT THE NCI FREDERICK CANCER RESEARCH FACILITY
3 N01 CO23910-05 GILDEN, RAYMOND V	08-02-82	83	7,013,488	1	70,135	PROGRAM RESOURCES, INC. OPERATIONS AT THE NCI FREDERICK FACILITY
3 N01 CO23910-06 GILDEN, RAYMOND V	08-02-82	83	274,116	1	2,741	PROGRAM RESOURCES, INC. OPERATIONS AT THE NCI FREDERICK FACILITY
3 N01 CO23910-07 GILDEN, RAYMOND V	08-02-82	83	15,812,422	1	158,124	PROGRAM RESOURCES, INC. OPERATIONS AT THE NCI FREDERICK FACILITY
3 N01 CO23910-10 GILDEN, RAYMOND V	08-02-82	83	5,862,113	1	58,621	PROGRAM RESOURCES, INC. OPERATIONS AT THE NCI FREDERICK FACILITY
3 N01 CO23910-11 GILDEN, RAYMOND V	08-02-82	83	8,601,830	1	86,018	PROGRAM RESOURCES, INC. OPERATIONS AT THE NCI FREDERICK FACILITY
5 N01 CO23910-12 GILDEN, RAYMOND V	08-02-82	84	3,747,306	1	37,473	PROGRAM RESOURCES, INC. OPERATIONS AT THE NCI FREDERICK FACILITY
3 N01 CO23910-14 GILDEN, RAYMOND V	08-02-82	84	456,525	1	4,565	PROGRAM RESOURCES, INC. OPERATIONS AT THE NCI FREDERICK FACILITY
5 N01 CO23910-15 GILDEN, RAYMOND V	08-02-82	84	3,000,000	1	30,000	PROGRAM RESOURCES, INC. OPERATIONS AT THE NCI FREDERICK FACILITY
5 N01 CO23910-17 GILDEN, RAYMOND V	08-02-82	84	5,129,000	1	51,290	PROGRAM RESOURCES, INC. OPERATIONS AT THE NCI FREDERICK FACILITY
3 N01 CO23910-18 GILDEN, RAYMOND V	08-02-82	84	18,223,986	1	182,240	PROGRAM RESOURCES, INC. OPERATIONS AT THE NCI FREDERICK FACILITY
5 N01 CO23910-19 GILDEN, RAYMOND V	08-02-82	84	151,920	1	1,519	PROGRAM RESOURCES, INC. OPERATIONS AT THE NCI FREDERICK FACILITY
3 N01 CO23910-20 GILDEN, RAYMOND V	08-02-82	84	2,816,918	1	28,169	PROGRAM RESOURCES, INC. OPERATIONS AT THE NCI FREDERICK FACILITY
5 N01 CO23910-21 GILDEN, RAYMOND V	08-02-82	84	3,790,108	1	37,901	PROGRAM RESOURCES, INC. OPERATIONS AT THE NCI FREDERICK FACILITY
		INSTITUTE TOTAL	89,947,412	15	899,473	

PROGRAM #N143; SOURCE: OPEN/PEND FILE & AIDS FILE

NIH AIDS PROJECTS FOR FISCAL YEARS 1983-84 BY INSTITUTE

NCI - Div. of Cancer Cause and Prevention --

GRANT NUMBER PI NAME	START DATE	FY	DOLLARS AWARDED	PERCENT TO AIDS	DOLLARS FOR AIDS	GRANTEE INSTITUTION TITLE OF PROJECT
5 N01 CP01044-06 CAHILL, JACK	09-27-80	83	1,931,539	5	96,577	WESTAT, INC. SUPPORT SERVICES FOR EPIDEMIOLOGY STUDIES
5 N01 CP01044-07 CAHILL, JACK	09-27-80	84	2,229,226	5	111,461	WESTAT, INC. SUPPORT SERVICES FOR EPIDEMIOLOGY STUDIES
3 N01 CP21007-03 BODNER, ANNE	04-01-82	83	346,602	12	41,592	BIOTECH RESEARCH LABORATORIES, INC. STORE SPECIMENS FROM PERSONS AT HIGH RISK OF CANCER
5 N01 CP21007-04 BODNER, ANNE	04-01-82	84	374,000	12	44,880	BIOTECH RESEARCH LABORATORIES, INC. STORE SPECIMENS FROM PERSONS AT HIGH RISK OF CANCER
1 Y01 CP30500-00 STRONG, DOUGLAS M	10-01-82	83	596,350	28	166,978	U.S. UNIFORMED SERVICES UNIV OF HLTH SCI IMMUNOLOGIC & IMMUOGENETIC STUDIES OF CANCER FAMILIES
3 Y01 CP30500-01 STRONG, DOUGLAS M	10-01-82	83	3,700	28	1,036	U.S. UNIFORMED SERVICES UNIV OF HLTH SCI IMMUNOLOGIC & IMMUNOGENETIC STUDIES OF CANCER FAMILIES
3 Y01 CP30500-02 STRONG, DOUGLAS M	10-01-82	84	400,667	28	112,187	U.S. UNIFORMED SERVICES UNIV OF HLTH SCI IMMUNOLOGIC & IMMUNOGENETIC STUDDIES OF HIGH ROSK CANCER
3 Y01 CP30500-03 STRONG, DOUGLAS M	06-01-84	84	232,683	28	65,151	U.S. UNIFORMED SERVICES UNIV OF HLTH SCI IMMUNOLOGIC & IMMUNOGENETIC STUDIES OF HIGH RISK CANCER
3 Y01 CP30500-04 STRONG, DOUGLAS M	06-01-84	84	84,000	28	23,520	U.S. UNIFORMED SERVICES UNIV OF HLTH SCI IMMUNOLOGIC & IMMUNOGENETIC STUDIES OF HIGH RISK CANCER
6 N01 CP31041-01 HANSEN, LOUISE	09-30-83	83	618,821	100	618,821	WESTAT, INC. CASE-CONTROL STUDY OF ORAL AND PHARYNGEAL CANCER
6 N01 CP31041-0101 HANSON, SUSAN	09-30-83	84	371,241	100	371,241	WESTAT, INC. CASE-CONTROL STUDY OF ORAL AND PHARYNGEAL CANCER
6 N01 CP31041-0102 HANSEN, LOUISE	09-30-83	84	209,000	100	209,000	WESTAT, INC. CASE-CONTROL STUDY OF ORAL AND PHARYNGEAL CANCER
6 N01 CP31041-02 GREENBERG, BARBARA	09-30-83	83	348,236	100	348,236	WESTAT, INC. SUPPORT SERVICE FOR A SURVEY OF T-CELL SUBSETS
6 N01 CP31041-0201 GREENBERG, BARBARA	09-30-83	84	33,912	100	33,912	WESTAT, INC. SUPPORT SERVICE FOR A SURVEY OF T-CELL SUBSETS
6 N01 CP31041-0202 GREENBERG, BARBARA	09-30-83	84	10,000	100	10,000	WESTAT, INC. SUPPORT SERVICE FOR A SURVEY OF T-CELL SUBSETS
6 N01 CP31041-03 DURAKO, STEPHEN J	09-28-84	84	654,606	100	654,606	WESTAT, INC. SUPPORT SERVICES FOR STUDY OF AIDS

PROGRAM #N143; SOURCE: OPEN/PEND FILE & AIDS FILE

NIH AIDS PROJECTS FOR FISCAL YEARS 1983-84 BY INSTITUTE

GRANT NUMBER PI NAME	START DATE	FY	DOLLARS AWARDED	PERCENT TO AIDS	DOLLARS FOR AIDS	GRANTEE INSTITUTION TITLE OF PROJECT
	INSTITUTE TOTAL		8,444,583	16	2,909,198	
National Heart Lung and Blood Institute (NHLBI)- Div. Blood Diseases and Resources						
1 Y02 HB30006-00 ALTER, HARRY	04-02-83	83	55,583	100	55,583	U.S. NATIONAL INSTITUTES OF HLTH STUDIES OF ACQUIRED DEFICIENCY SYNDROME (AIDS)
2 Y02 HB30006-01 ALTER, HARRY	03-28-84	84	60,000	100	60,000	U.S. NATIONAL INSTITUTES OF HLTH STUDIES OF AIDS
1 Y02 HB30018-00 HENDRICKSON, ROY	09-16-83	83	138,595	100	138,595	U.S. NATIONAL INSTITUTES OF HLTH NHLBI/DRR - SIMIAN ACQUIRED IMMUNODEFICIENCY SYNDROME
1 Y01 HB30034-00 EVATT, BRUCE	10-01-82	83	140,000	100	140,000	U.S. CENTERS FOR DISEASE CONTROL NHLBI AGREEMENT WITH CDC: AIDS
4 N01 HB47002-00 MOSLEY, JAMES W	05-25-84	84	210,000	100	210,000	UNIVERSITY OF SOUTHERN CALIFORNIA SERUM RESPOSITORY FOR HTLV-111 TESTING -AIDS
3 N01 HB47002-01 MOSLEY, JAMES W	05-25-84	84	282,000	100	282,000	UNIVERSITY OF SOUTHERN CALIFORNIA SERUM RESPOSITORY FOR HTLV-111 TESTING -AIDS
3 N01 HB47002-02 MOSLEY, JAMES W	05-25-84	84	62,596	100	62,596	UNIVERSITY OF SOUTHERN CALIFORNIA SERUM RESPOSITORY FOR HTLV-111 TESTING -AIDS
1 N01 HB47003-00 MOSLEY, JAMES W	09-30-84	84	2,345,000	100	2,345,000	UNIVERSITY OF SOUTHERN CALIFORNIA BLOOD USE IMMUNE FUNCTION CHANGE RELATION TO AIDS
	INSTITUTE TOTAL		3,293,774	8	3,293,774	
National Heart Lung and Blood Institute						
5 P01 HL09011-20 KELLNER, AARON	03-01-76	83	1,371,513	2	27,430	NEW YORK BLOOD CENTER A RESEARCH AND RESOURCE PROGRAM IN BLOOD
3 P01 HL09011-20S1 KELLNER, AARON	03-01-76	83	705,891	2	14,118	NEW YORK BLOOD CENTER A RESEARCH AND RESOURCE PROGRAM IN BLOOD
5 P01 HL09011-21 KELLNER, AARON	03-01-76	84	1,705,963	2	34,119	NEW YORK BLOOD CENTER A RESEARCH AND RESOURCE PROGRAM IN BLOOD
5 P50 HL26309-03 ROBERTS, HAROLD R	05-01-81	83	853,263	3	25,598	UNIVERSITY OF NORTH CAROLINA CHAPEL HILL SPECIALIZED CENTER OF RESEARCH IN THROMBOSIS
3 P50 HL26309-03S1 ROBERTS, HAROLD R	05-01-81	84	4,197	3	126	UNIVERSITY OF NORTH CAROLINA CHAPEL HILL SPECIALIZED CENTER OF RESEARCH IN THROMBOSIS
5 P50 HL26309-04 ROBERTS, HAROLD R	05-01-81	84	524,127	3	15,724	UNIVERSITY OF NORTH CAROLINA CHAPEL HILL SPECIALIZED CENTER OF RESEARCH IN THROMBOSIS
3 P50 HL26309-04S1 ROBERTS, HAROLD R	05-01-81	84	244,694	3	7,341	UNIVERSITY OF NORTH CAROLINA CHAPEL HILL SPECIALIZED CENTER OF RESEARCH IN THROMBOSIS

PROGRAM #N143; SOURCE: OPEN/PEND FILE & AIDS FILE

NIH AIDS PROJECTS FOR FISCAL YEARS 1983-84 BY INSTITUTE

GRANT NUMBER PI NAME	START DATE	FY	DOLLARS AWARDED	PERCENT TO AIDS	DOLLARS FOR AIDS	GRANTEE INSTITUTION TITLE OF PROJECT
1 R01 HL31015-01 MONTGOMERY, ROBERT R, JR	07-01-83	83	100,801	100	100,801	MEDICAL COLLEGE OF WISCONSIN ACQUIRED IMMUNOLOGIC ABNORMALITIES IN HEMOPHILIA
1 R01 HL32432-01 BOREK, ERNEST	04-01-84	84	121,754	100	121,754	AMC CANCER RESEARCH CENTER BIOCHEMICAL MARKERS FOR LATENT CARRIERS OF AIDS
1 R01 HL32434-01 BLASER, MARTIN J	04-01-84	84	49,389	100	49,389	UNIVERSITY OF COLORADO HLTH SCIENCES CTR DETECTION OF AIDS-AGENT CARRIERS BY SEROLOGIC ASSAYS
1 R01 HL32453-01 ENGLEMAN, EDGAR G	04-01-84	84	164,598	100	164,598	STANFORD UNIVERSITY DETECTION OF THE CARRIER STATE OF AIDS
1 R01 HL32471-01 RICHMAN, DOUGLAS D	04-01-84	84	199,602	100	199,602	UNIVERSITY OF CALIFORNIA SAN DIEGO NUCLEIC ACID HYBRIDIZATION TO DETECT AIDS RELATED AGENTS
1 R01 HL32473-01 PREBLE, OLIVIA T	07-01-84	84	179,786	100	179,786	U.S. UNIFORMED SERVICES UNIV OF HLTH SCI ACID-LABILE ALPHA INTERFERON IN PRECLINICAL AIDS
1 R01 HL32477-01 PERKINS, HERBERT A	05-15-84	84	175,428	100	175,428	SAN FRANCISCO MEDICAL SOCIETY LABORATORY DETECTION OF AIDS IN HEALTHY CARRIERS
1 R01 HL32505-01 DREESMAN, GORDON R	04-01-84	84	174,410	100	174,410	SOUTHWEST FOUNDATION FOR BIOMEDICAL RES ASSAY METHODS TO DETECT ANTIGENIC MARKERS FOR AIDS
	INSTITUTE TOTAL		6,575,416	15	1,290,224	
	GRAND TOTAL		147,849,861	243	42,821,224	

PROGRAM #N143; SOURCE: OPEN/PEND FILE & AIDS FILE

11-20-84

DIVISION OF RESEARCH RESOURCES
AIDS RESEARCH
1984 SUBPROJECT SUPPORT BY PROGRAM

DIVISION OF RESEARCH RESOURCES PROGRAMS	--- OTHER BID --- DOLLARS	SUBPROJ	----- DRR ----- DOLLARS	SUBPROJ	TOTAL GRANTS
ANIMAL RESOURCES			858,138	23	9
BIOMEDICAL INSTRUMENTATION			54,500	3	3
BIOMEDICAL RESEARCH SUPPORT			85,826	17	16
CLINICAL RESEARCH CENTERS			357,686	24	17
DIVISION OF RESEARCH RESOURCES	$		$ 1,356,150	67	45

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                                      DIVISION OF RESEARCH RESOURCES
                                               AIDS RESEARCH
                                     1984 SUBPROJECT SUPPORT BY PROGRAM
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GRANT NUMBER  PROGRAM DIRECTOR  SUBPROJECT FUNDS           INSTITUTION              CITY           STATE                 TOTAL
SUBPROJ    INVESTIGATOR         BID        DRR               TITLE                                                      DRR AWARI
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P40RR00361-17 KALTER, SEYMOUR S      09/84-09/85 SOUTHWEST FOUNDATION FOR BIOMEDICAL RSAN ANTONIO      TEXAS                66,547
43326 KALTER, S S                         38,994    SIMIAN VIRUS DIAGNOSTIC LABORATORY (SAIDS, MEASLES, HERPES)

P40RR00393-17 JACOBY, ROBERT O       01/84-12/84 YALE UNIVERSITY                   NEW HAVEN       CONNECTICUT         489,475
43044 SMITH, ABIGAIL L                      150    IMMUNOSUPPRESSION INDUCED BY MVM I AN ANIMAL MODEL OF AIDS

P51RR00163-25 LASTER, LEONARD        07/84-04/85 MEDICAL RESEARCH FOUNDATION OF OREGONPORTLAND      OREGON            4,301,390
                                          75,000    SUPPLEMENTAL FUNDS
45094 SHIIGI, STANLEY M                   39,516    NONHUMAN PRIMATE MODELS FOR IMMUNODEFICIENCY SYNDROMES

P51RR00164-23 WALSH, JOHN J          05/84-04/85 TULANE UNIVERSITY OF LOUISIANA      NEW ORLEANS     LOUISIANA         2,366,703
                                          20,000    SUPPLEMENTAL FUNDS
45120 RANGAN, SETLUR R                    57,658    CYCLOSPORIN A AND CYTOMEGALOVIRUS INFECTION

P51RR00165-24 HATCHER, CHARLES R, J05/84-04/85 EMORY UNIVERSITY                   ATLANTA         GEORGIA
45231 MCCLURE, HAROLD M                   28,612    CLINICAL IMMUNOLOGY AND SURVEY OF MACAQUE COLONY FOR AIDS LIKE DISEASE
45232 MCCLURE, HAROLD M                   28,612    CHIMPANZEES EXPOSED TO HUMAN AIDS
                                          20,000    SUPPLEMENTAL FUNDS

P51RR00166-23 LEIN, JOHN N           07/84-04/85 UNIVERSITY OF WASHINGTON           SEATTLE         WASHINGTON
45585 MORTON, WILLIAM R                   19,408    IMMUNOLOGY OF ENZOOTIC RETROPERITONEAL FIBROMATOSIS (ERF)
                                          75,000    SUPPLEMENTAL FUNDS

P51RR00167-24 BOCK, ROBERT M         07/84-04/85 UNIVERSITY OF WISCONSIN MADISON    MADISON         WISCONSIN         2,548,580
                                          20,000    SUPPLEMENTAL FUNDS
45292 UNO, HIDEO                          28,239    KAPOSI SARCOMA LIKE LESIONS IN PIGTAILED MACAQUES

P51RR00168-23 TOSTESON, DANIEL C     05/84-04/85 HARVARD UNIVERSITY                 BOSTON          MASSACHUSETTS
45367 CHALIFOUX, L V                      25,700    MORPHOLOGIC CHANGES IN LYMPH NODES OF MACAQUES W/ AN IMMUNODEFICIENCY SYNDROME
45371 LETVIN, NORMAN L                    25,700    TRANSMISSION OF NATURALLY OCCURRING LYMPHOMA AND MACAQUE AIDS IN MACAQUE MONKEYS
45354 LETVIN, NORMAN L                    25,700    ACQUIRED IMMUNODEFICIENCY SYNDROME IN A COLONY OF MACAQUE MONKEYS
45357 LETVIN, NORMAN L                    25,700    TRANSMISSION OF MACAQUE AIDS BY MEANS OF INOCULATION OF MACAQUE LYMPHOMA TISSUE
45389 DANIEL, M D                         25,700    IMMUNODEFICIENCY SYNDROME IN MACAQUES & THE ISOLATION OF A NEW TYPE D RETROVIRUS
                                          95,000    SUPPLEMENTAL FUNDS
45361 KING, NORVAL W, JR                  25,700    HISTOPATHOLOGIC CHANGES IN MACAQUES WITH AN ACQUIRED IMMUNODEFICIENCY SYNDROME
45386 DANIEL, M D                         25,700    ATTEMPTS TO ISOLATE A RETROVIRUS FROM HUMAN AIDS PATIENTS

P51RR00169-23 RHODE, EDWARD A        05/84-04/85 UNIVERSITY OF CALIFORNIA DAVIS     DAVIS           CALIFORNIA        2,884,184
                                          95,000    SUPPLEMENTAL FUNDS
45462 GARDNER, M                          37,049    SIMIAN ACQUIRED IMMUNE DEFICIENCY SYNDROME (SAIDS)
ANIMAL RESOURCES                         858,138       23  DRR SUBPROJ                          9   DRR GRANTS
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                                                           BID SUBPROJ                              DRR GRANTS W/BID FUNDS
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                                                DIVISION OF RESEARCH RESOURCES
                                                        AIDS RESEARCH
                                               1984 SUBPROJECT SUPPORT BY PROGRAM

GRANT NUMBER  PROGRAM DIRECTOR  SUBPROJECT FUNDS          INSTITUTION             CITY            STATE                 TOTAL
SUBPROJ   INVESTIGATOR          BID       DRR               TITLE                                                    DRR AWARD

S10RR01945-01 CAMBIER, JOHN C       01/84-12/84 NATIONAL JEWISH HOSP & RES CTR-NAT'L DENVER          COLORADO            215,000
10874 KIRKPATRICK, CHARLES                32,250    CS: PATHOGENESIS OF AIDS (LYMPHADEOPATHY, HEPATITIS B, HEMOPHILIA A, HOMOSEXUAL)

S10RR01959-01 KELLER, ROBERT H      01/84-12/84 MEDICAL COLLEGE OF WISCONSIN        MILWAUKEE       WISCONSIN            69,000
11052 ASTER, RICHARD H                    10,350    CS UPGRADE: T SUBSETS & IMMUNOMODULATOR EFFECTS, AIDS, HEMOPHILIACS & HOMOSEXUAL

S10RR02034-01 KONIGSBERG, WILLIAM H01/84-12/84 YALE UNIVERSITY                      NEW HAVEN       CONNECTICUT         238,000
11843 SUMMERS, WILLIAM C                  11,900    PROTEIN SEQ: GENETICS OF HSV THYMIDINE KINASE IN DESIGN OF CHEMOTHERAPEUTICS
BIOMEDICAL INSTRUMENTATION                54,500       3  DRR SUBPROJ                      3   DRR GRANTS
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                                                     BID SUBPROJ                         DRR GRANTS W/BID FUNDS
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DIVISION OF RESEARCH RESOURCES
AIDS RESEARCH
1984 SUBPROJECT SUPPORT BY PROGRAM

GRANT NUMBER SUBPROJ	PROGRAM DIRECTOR INVESTIGATOR	SUBPROJECT BID	FUNDS DRR	INSTITUTION TITLE	CITY	STATE	TOTAL DRR AWAR
S07RR05359-23	LEONARD, FRED	04/84-03/85		GEORGE WASHINGTON UNIVERSITY	WASHINGTON	DIST OF COL	151,834
61834	SCHULOF, RICHARD		2,664	PILOT STUDY OF THYMOSIN THERAPY IN PRE AIDS			
S07RR05363-23	FOGEL, BERNARD J	04/84-03/85		UNIVERSITY OF MIAMI	MIAMI	FLORIDA	237,884
57515	KLIMAS, NANCY G		8,432	IMMUNOSUPRESSIVE FACTORS IN SERUM OF ACQUIRED IMMUNODIFICIENCY SYNDROME PATIENTS			
57522	MCKINNEY, CHURCHILL		8,231	AUTOIMMUNE ANTI T HELPER ACTIVITY IN AIDS PATIENTS			
S07RR05392-23	MCCOLLUM, ROBERT W	04/84-03/85		DARTMOUTH COLLEGE	HANOVER	NEW HAMPSHIRE	155,007
59372	KASPER, LLOYD H		2,001	TOXOPLASMA GONDII:ANTIGENIC CHARACTERIZATION AND IMMUNITY			
S07RR05399-23	FARBER, SAUL J	04/84-03/85		NEW YORK UNIVERSITY	NEW YORK	NEW YORK	261,265
56333	FRIEDMAN-KIEN, ALVIN		7,557	PATHOBIOLOGY OF DISSEMINATED AND LOCALIZED KAPOSIS SARCOMA			
S07RR05400-23	NAUGHTON, JOHN P	04/84-03/85		STATE UNIVERSITY OF NEW YORK AT BUFFA	BUFFALO	NEW YORK	176,094
56353	BRASS, CORSTIAAN		1,951	PATHOGEN FACTORS & EFFECTS OF TREATMENT IN A MOUSE MODEL OF SYSTEMIC CANDIDIASIS			
S07RR05445-23	GOLDBERG, ALAN M	04/84-03/85		JOHNS HOPKINS UNIVERSITY	BALTIMORE	MARYLAND	212,271
59407	GOINGS, STELLA A		306	PARCOVIRIDAE & OTHER VIRUSES IN THE ACQUIRED IMMUNE DEFICIENCY			
S07RR05487-22	COFFMAN, JAY D	04/84-03/85		UNIVERSITY HOSPITAL (BOSTON)	BOSTON	MASSACHUSETTS	57,513
54413	HAUSER, WILLIAM E		5,000	ROLE OF NATURAL KILLER CELLS IN IMMUNITY TO TOXOPLASMOSIS			
S07RR05513-22	KRUPP, MARCUS A	04/84-03/85		PALO ALTO MEDICAL FOUNDATION RES INST	PALO ALTO	CALIFORNIA	34,791
56883	LUFT, BENJAMIN J		22,241	IMMUNITY IN ACQUIRED IMMUNODEFICIENCY SYNDROME			
S07RR05593-17	RUSHMER, DONALD S	04/84-03/85		GOOD SAMARITAN HOSP & MED CTR(PRTLND,	PORTLAND	OREGON	47,945
51220	LEVINSON, WENDY		1,823	PARASITIC ILLNESS IN HOMOSEXUAL MEN			
S07RR05604-07	GORTNER, SUSAN R	04/84-03/85		UNIVERSITY OF CALIFORNIA SAN FRANCISC	SAN FRANCISCO	CALIFORNIA	21,533
57088	LESSOR, ROBERTA		4,166	RISK SHARING AMONG NURSES ON AIDS UNIT: SOCIAL PSYCHOLOGICAL PROCESSES			
S07RR05649-18	AXELROD, DAVID E	04/84-03/85		NEW YORK STATE DEPARTMENT OF HEALTH	ALBANY	NEW YORK	93,011
57149	FLAHERTY, LORRAINE		6,903	ASSAY METHODS TO DETECT CARRIER STATE OF AIDS			
S07RR05736-12	KUSCHNER, MARVIN	04/84-03/85		STATE UNIVERSITY NEW YORK STONY BROOK	STONY BROOK	NEW YORK	195,463
58606	STEIGBIGEL, ROY T		9,180	PATHOGENESIS OF ACQUIRED IMMUNODEFICIENCY SYNDROME			
S07RR05842-05	HENSON, PETER M	04/84-03/85		NATIONAL JEWISH HOSP & RES CTR-NAT'L	DENVER	COLORADO	149,041
59837	GANGADHARAM, PATTISA		2,840	EXPERIMENTAL CHEMOGHERAPY OF MYCOBACTERIUM INTRACELLULARE DISEASE			
S07RR07015-19	BOCKELMAN, CHARLES K	04/84-03/85		YALE UNIVERSITY	NEW HAVEN	CONNECTICUT	225,869
60114	NOVICK, ALVIN		176	ETHNICS DISTRIBUTION OF AIDS			
S07RR07026-19	ALLEN, RICHARD D	04/84-03/85		UNIVERSITY OF HAWAII AT MANOA	HONOLULU	HAWAII	102,805
55056	CHING, CLARA Y		1,841	NATURAL KILLER FUNCTION IN ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS)			

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                                                                                                  11-20-84
                                        DIVISION OF RESEARCH RESOURCES
                                                 AIDS RESEARCH
                                      1984 SUBPROJECT SUPPORT BY PROGRAM

GRANT NUMBER  PROGRAM DIRECTOR  SUBPROJECT FUNDS          INSTITUTION             CITY              STATE                 TOTAL
SUBPROJ    INVESTIGATOR         BID        DRR              TITLE                                                      DRR AWARD

S07RR07206-03 RATHGE, RICHARD W    04/84-03/85 NORTH DAKOTA STATE UNIVERSITY      FARGO             NORTH DAKOTA          15,913
52715 GABRIELSON, DAVID A                  514    TOXOPLASMA GONDII: EXOTOXIN AND ITS ITS VACCINE POTENTIAL
BIOMEDICAL RESEARCH SUPPORT             85,826      17  DRR SUBPROJ                          16   DRR GRANTS
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                                                    BID SUBPROJ                               DRR GRANTS W/BID FUNDS


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                                                                                                                            11-20-8
                                                    DIVISION OF RESEARCH RESOURCES
                                                            AIDS RESEARCH
                                                  1984 SUBPROJECT SUPPORT BY PROGRAM

GRANT NUMBER  PROGRAM DIRECTOR  SUBPROJECT FUNDS           INSTITUTION             CITY              STATE                  TOTAL
SUBPROJ   INVESTIGATOR          BID        DRR                TITLE                                                       DRR AWAR

M01RR00030-23 ANLYAN, WILLIAM G    12/83-11/84 DUKE UNIVERSITY                      DURHAM            NORTH CAROLINA     1,372,27
20021 GALLIS, HARRY A                   17,551     5 FLUOROCYTOSINE & AMPHOTERICIN B IN CRYPTOCOCCAL MENINGITIS

M01RR00032-24 PITTMAN, JAMES A, JR 12/83-11/84 UNIVERSITY OF ALABAMA IN BIRMINGHAM  BIRMINGHAM        ALABAMA              911,73
20071 DISMUKES, WILLIAM E               83,721     COMPARISON OF TWO REGIMENS OF 5 FC + AMB IN THERAPY OF CRYPTOCOCCAL MENINGITIS
20078 DISMUKES, WILLIAM E               20,244     2 DOSAGE REGIMENS OF ORAL KETOCONAZOLE IN BLASTOMYCOSIS OR HISTOPLASMOSIS

M01RR00047-24 MEIKLE, THOMAS H     12/83-11/84 CORNELL UNIVERSITY MEDICAL CENTER    NEW YORK          NEW YORK           1,587,93
20751 ROBERTS, RICHARD J                 5,533     COLLABORATIVE STUDIES OF AIDS/KAPOSIS SARCOMA

M01RR00051-23 SCHWARZ, M ROY       07/84-11/84 UNIVERSITY OF COLORADO HLTH SCIENCES DENVER            COLORADO           1,440,94
20908 HASIBA, UTE                        3,038     EVALUATION OF IMMUNE STATUS IN PATIENTS WITH HEMOPHILIA
20928 ROBINSON, WILLIAM A                1,199     SINGLE STUDY AIDS SYNDROME MANIFESTED BY A KAPOSIS SARCOMA REFRACTORY

M01RR00065-22 STEINFELD, JESSE L   12/83-11/84 VIRGINIA COMMONWEALTH UNIVERSITY     RICHMOND          VIRGINIA             675,48
21299 KERKERING, THOMAS M                  174     5 FLUOROCYTOSINE & AMPHOTERICIN B IN THERAPY OF CRYPTOCOCCAL MENINGITIS

M01RR00068-22 KNOWLES, HARVEY C, JR12/83-11/84 UNIVERSITY OF CINCINNATI             CINCINNATI        OHIO               1,400,028
21384 SOLINGER, ALAN M                   7,447     INVESTIGATION OF PATHOGENESIS OF ACQUIRED IMMUNODEFICIENCY SYNDROMES

M01RR00073-22 LEVIN, WILLIAM C     12/83-11/84 UNIVERSITY OF TEXAS MED BR GALVESTON GALVESTON         TEXAS                691,510
21566 JORIZZO, JOSEPH L                  4,481     IBUPROFEN (MOTRIN) AS AN IMMUNE ENHANCER IN CHRONIC MUCOCUTANEOUS CANDIDOSIS

M01RR00083-22 SCHMID, RUDI         12/83-11/84 UNIVERSITY OF CALIFORNIA SAN FRANCISCSAN FRANCISCO     CALIFORNIA         1,124,620
21805 VOLBERDING, PAUL                  30,322     PHASE II TRIAL OF ALPHA 2 INTERFERON IN KAPOSIS SARCOMA

M01RR00096-24 HOLLANDER, CHARLES S 12/83-11/84 NEW YORK UNIVERSITY                  NEW YORK          NEW YORK           2,501,740
21990 BORKOWSKY, WILLIAM                 3,096     LITHIUM ION AS AN IMMUNOLOGICAL ADJUVANT; IMMUNODEFICIENCY
22022 FRIEDMAN-KIEN, ALVIN              12,384     GAMMA INTERFERON TREATMENT OF KAPOSIS SARCOMA

M01RR00102-21 KAPPAS, ATTALLAH     12/83-11/84 ROCKEFELLER UNIVERSITY               NEW YORK          NEW YORK           2,102,919
22091 LAURENCE, JEFFREY                  5,020     ACQUIRED IMMUNE DEFICIENCY SYNDROME

M01RR00125-21 EBBERT, ARTHUR, JR   12/83-11/84 YALE UNIVERSITY                      NEW HAVEN         CONNECTICUT        2,587,089
22262 DWYER, JOHN M                     10,307     CELL MEDIATED IMMUNE DEFICIENCY DIAGNOSIS & TREATMENT WITH TRANSFER FACTOR

M01RR00645-13 TAPLEY, DONALD F     12/83-11/84 COLUMBIA UNIVERSITY NEW YORK         NEW YORK          NEW YORK           1,121,269
23129 APPEL, GERALD B                    4,221     THE STUDY OF IMMUNOLOGIC ABNORMALITIES IN AIDS PATIENTS ON DIALYSIS

M01RR00722-12 ROSS, RICHARD S      12/83-11/84 JOHNS HOPKINS UNIVERSITY             BALTIMORE         MARYLAND             292,817
23213 POLK, FRANK                          576     LONGITUDINAL STUDIES OF THE ACQUIRED IMMUNE DEFICIENCY SYNDROME

M01RR00827-10 PETERSDORF, ROBERT G 07/84-11/84 UNIVERSITY OF CALIFORNIA SAN DIEGO   LA JOLLA          CALIFORNIA           919,329
23409 KAGNOFF, MARTIN F                    515     INTESTINAL IMMUNE FUNCTION IN HOMOSEXUAL MALES WITH/WITHOUT AIDS

M01RR00865-11 MELLINKOFF, SHERMAN M12/83-11/84 UNIVERSITY OF CALIFORNIA LOS ANGELES LOS ANGELES       CALIFORNIA
23595 GOTTLIEB, MICHAEL S               40,444     PHASE II TRIAL OF ALPHA 2 INTERFERON IN KAPOSIS SARCOMA
                                                         PAGE     5
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                                     DIVISION OF RESEARCH RESOURCES                                          11-20-8
                                              AIDS RESEARCH
                                   1984 SUBPROJECT SUPPORT BY PROGRAM
_____________________________________________________________________________________________________________________
GRANT NUMBER  PROGRAM DIRECTOR  SUBPROJECT FUNDS              INSTITUTION                CITY            STATE                 TOTAL
SUBPROJ   INVESTIGATOR          BID        DRR                   TITLE                                                     DRR AWAR
_____________________________________________________________________________________________________________________
M01RR00865-11 MELLINKOFF, SHERMAN M12/83-11/84 UNIVERSITY OF CALIFORNIA LOS ANGELES LOS ANGELES     CALIFORNIA            990,27
23571 MITSUYASU, RONALD T                3,331    BONE MARROW TRANSPLANTATION IN TWINS: KAPOSIS SARCOMA & AIDS
23588 SAXON, ANDREW                     53,291    MODIFIED SERUM IMMUNOGLOBULIN INFUSION: DOSE STUDY FOR IMMUNODEFICIENCY SYNDROME
23594 GOTTLIEB, MICHAEL S                4,758    ALPHA 2 INTERFERON IN AN ACQUIRED T CELL IMMUNODEFICIENCY (AID)

M01RR00997-09 NAPOLITANO, LEONARD M12/83-11/84 UNIVERSITY OF NEW MEXICO ALBUQUERQUE ALBUQUERQUE     NEW MEXICO            773,49
23738 SIMON, TOBY                        3,442    EFFICACY OF IV GAMMA GLOBULIN TO PREVENT CONGENITAL & ACQUIRED IMMUNODEFICIENCY

M01RR01346-03 STEIN, JAY H        07/84-11/84 UNIVERSITY OF TEXAS HLTH SCI CTR SAN SAN ANTONIO      TEXAS
23971 GRAYBILL, JOHN R                  25,997    PHASE III STUDIES OF KETOCONAZOLE IN COCCIDIOMYCOSIS
23967 GRAYBILL, JOHN R                  16,594    PHASE II STUDIES OF KETOCONAZOLE IN COCCIDIOIDAL MENINGITIS
CLINICAL RESEARCH CENTERS              357,686      24  DRR SUBPROJ                      17   DRR GRANTS
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                                                        BID SUBPROJ                           DRR GRANTS W/BID FUNDS
DIVISION OF RESEARCH RESOURCES       1,356,150      67  DRR SUBPROJ                      45   DRR GRANTS
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                                                        BID SUBPROJ                           DRR GRANTS W/BID FUNDS
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SECTION 6: Office of the Assistant Secretary for Health Office of Public Affairs AIDS Public Information Plan for Fiscal Year 1985[2]

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[2] Also includes descriptions of public information activities of NIH, NIDA, NIMH, and CDC.

BACKGROUND

Public information and education activities regarding Acquired Immune Deficiency Syndrome (AIDS) have been conducted by various PHS components since the first AIDS cases were reported in 1981; a formal public information plan was prepared in 1983. In September 1983, this plan was refined to include stated objectives, defined target audiences, and a list of specific projects, activities and materials to be prepared or conducted by PHS components during Fiscal Year 1984. It was subsequently approved by the Assistant Secretary for Health, and a budget was provided for the program. Significant activities are described in the AIDS Operational Plan as updated July 1, 1984.

With the identification of HTLV-III as the probable AIDS cause by PHS scientists in April 1984, modifications in existing public information materials were made and revisions became necessary in the initial plan, reflecting the imminent testing of a blood test for HTLV-III antibodies and subsequent availability of the test for the public and to specific risk groups. Also, experience with the initial plan and with risk groups indicated additional needs and opportunities for public information and education activity. The revised plan also makes fuller use of resources outside PHS, such as health agencies, organizations, facilities and community groups in promoting, conducting, and financing AIDS information and education activities. The revised plan reflects the input of individual agencies through the Information and Education Panel of the PHS Executive Task Force on AIDS.

OBJECTIVES: To provide information to the American public regarding Acquired Immune Deficiency Syndrome (AIDS) sufficient to create a widespread awareness and understanding of the nature of the syndrome, its probable cause and test(s) for its detection, its suspected means of transmission, the relative threat it poses to specific populations and to the public health, and precautions recommended for avoiding contracting the syndrome.

TARGET AUDIENCES: The nature and effects of AIDS and the public response experienced to date regarding attitudes toward the syndrome and to risk groups indicate the desirability of targeting selected information and appropriate messages to several audiences. Following are brief descriptions of those audiences and messages:

I. General Public, male and female, aged 14 and older, not specifically identified as being at risk -- This group includes certain subgroups that will require additional information and targeted messages, but in general it requires a basic awareness of AIDS as being primarily an affliction of the risk groups, information on the incidence of the syndrome among the risk groups and the total population, the availability of test(s) for its detection, the means of transmission, and the safety of blood donation and blood transfusion as it relates to contracting AIDS. The purpose of providing this information is to allay fear in the general public regarding the likelihood of contracting AIDS, particularly where such fear needlessly reduces blood donations, interferes with patient acceptance of medically necessary blood transfusions, and stigmatizes risk groups so as to interfere with their functions and relationships in society. Subgroups of this target audience, not treated separately elsewhere, include:

--Blood donors not at risk;

--Persons who frequently encounter at risk populations as a result of their type of work, place of work or residence, or recreational pursuits;

--Persons who encounter populations at risk as a result of family relationships or friendships (not including sexual partners).

--Participants in AIDS-related studies regarding blood transfusions, blood test(s) for HTLV-III antibodies, AIDS vaccine, sexual activity, and mental health aspects.

II. Homosexual and Bisexual Male Portion of the General Public -- This group requires AIDS information sufficient to understand the nature of the syndrome, whether their sexual activity renders them among the at-risk population, the precautions recommended for avoiding contracting the syndrome, the availability of test(s) for HTLV-III antibodies, symptoms of the syndrome, and awareness that significant effort is being applied to developing a vaccine for AIDS and improved treatment for AIDS patients.

III. Abusers of Intravenous Drugs -- This group needs to be informed of the dangers of AIDS, the risk of acquiring the syndrome through use of infected needles, tests for HTLV-III antibodies, and symptoms of AIDS.

IV. Recent Haitian Immigrants -- In addition to knowledge of the syndrome, related tests, and its symptoms, this group ~~needs~~ to understand what the "at risk" designation means, precautions for avoiding contracting the syndrome, and sufficient understanding of the means of AIDS transmission so that they can counter misconceptions about the syndrome directed against them.

V. Hemophilia Patients -- These frequent recipients of blood and blood products need to know the risks involved regarding the potential for contracting AIDS. The group should have access to understandable explanations of the syndrome, related test(s), and precautions that blood laboratories take to protect the purity of their products.

VI. Health Workers -- This audience encompasses a wide range of occupations and professions that require information on treating AIDS patients and on self-protection against the syndrome. There is a particular need to correct misconceptions about AIDS among this group that interfere with providing good medical care to AIDS patients.

VII. Other Workers Whose Jobs Bring Them In Close Contact With At-Risk Populations -- This group, which includes such occupations as police, prison and other security guards, certain laundry and custodial workers, and similar service personnel, usually has less health information and understanding than most of the audiences in category VI. The group needs basic information about the nature of AIDS and its means of transmission so that they will not harbor unnecessary fears about their work and the at-risk individuals they deal with.

STRATEGIES: To date, all PHS agencies have participated in some way in public information and education activities regarding AIDS. Activities have been coordinated by the Office of Public Affairs, OASH, which has also directly conducted many of the more than two dozen individual projects comprising the previous AIDS Public Information Plan.

Information for professionals has been disseminated via the MMWR, journal articles, bulletins, pamphlets, media interviews and numerous workshops on AIDS conducted by the agencies and attended by outside consultants, organizations and the public. Some 40,000 copies of the MMWR--which has carried articles on AIDS epidemiology and etiology, PHS recommendations and precautions for health workers--are regularly distributed to the health community. In addition, reprints of these articles have been distributed to community health centers, other health facilities and drug treatment centers. CDC has also developed AIDS videotapes and information materials for venereal disease project areas, STD prevention training centers, PHS Regional Offices and professional groups. Videotapes have been produced or are in production by OPA, with CDC and NIH for release this fall to hospital laboratory and nursing staff audiences, public safety personnel and drug treatment center staffs, and the public. These will be offered for sale and distributed through the National Audiovisual Center. CDC has also distributed more than 40,000 slides for use in clinical and public health training, use by the media and for public health education programs. National and regional conferences have been sponsored by NIH and CDC to provide clinical information to primary care physicians, nurses, laboratory technicians and other allied health personnel, and state and local health officials. Special meetings have been sponsored by the agencies to exchange information on special aspects of AIDS, such as transfusion-associated cases, safety of clotting factor concentrates, simian AIDS, the needs of drug abuse treatment centers and community centers, and ethical issues in AIDS-related studies.

Early efforts aimed at the populations at risk and at the public focused on providing information quickly through the news media, including the gay press, which carried articles, broadcast news and features and offered documentary programs based on PHS-provided information about AIDS. These channels also promoted the national AIDS toll-free hotline (800-342-AIDS) operated by PHS. The hotline is available to the public for AIDS information 24 hours a day and has received more than 600,000 calls, most of them from individuals in the populations at risk. The National Institute of Drug Abuse (NIDA) has directed materials about AIDS to drug users through drug treatment centers. OPA has awarded a contract to a Haitian community group in Miami, Fla., to conduct AIDS information activities in the Haitian community there. PHS information materials have been sent in bulk to Haitian organizations to enable them to conduct education programs among their members. PHS has also worked with organizations representing hemophiliacs to provide information to that group.

The public has been informed through PHS interviews with the news media, briefings and press conferences, and an assortment of materials ranging from small reference cards and fact sheets to booklets and pamphlets. The materials assure that the public understands that persons outside the identified risk groups are at very low risk of acquiring the disease and that casual contact with persons in the risk groups poses no danger to the public health. The materials are also intended to help allay public concerns regarding the safety of donating blood and receiving blood transfusions. PHS officials have participated in countless television and radio interviews to discuss AIDS. Exhibits have been built by the Health Resources and Services Administration (HRSA) for use by AIDS-related PHS components at meetings and conventions for health professionals and other appropriate audiences.

The reporting of HTLV-III as the probable cause of AIDS necessitates revising or supplementing all AIDS information material and the development of new items for specific purposes. In addition, greater efforts are necessary for some target audiences, specifically more effort targeted to drug users, their families and treatment center staff. Also, new efforts are needed to explain the HTLV-III antibody test to the public and to potential participants in various research projects, as well as to blood donors and recipients.

Cost estimates for the FY 1984 public information activities amounted to $197,850, in addition to at least $43,000 in services and expenses contributed by individual components. To ensure best use of FY 1985 funds and to maximize results of new materials and projects, the revised plan emphasizes sharing of materials, development of prototypes for reproduction by others, and the involvement of other agencies, organizations and facilities in the private and public sector for production, reproduction and distribution of materials. For example, PHS has mounted a collaborative project with the U.S. Conference of Mayors to identify the most effective educational strategies and materials in use in various cities and communities and to share those materials and techniques with health officials throughout the country in mounting their own AIDS information programs.

FY 1985 Information Projects/Activities/Materials Concerning Acquired Immune Deficiency Syndrome

1. Blood Test Materials (fact sheets and cards): This will include descriptions of the test(s) for HTLV-III antibodies, expected to be available and in use by the end of 1984. Prototype materials will be developed for use by physicians, health care facilities, blood banks, blood collection agencies, and similar appropriate entities. Although supplies will be made available in bulk quantities, entities will be encouraged to use "camera copy" reproducibles and print their own materials.

During the research period, it will be necessary to develop film and/or videotape footage describing the blood test, for use by the news media and for patient education and participant education purposes. This would be in addition to the usual press releases and background explanatory statements used to explain PHS activities.

2. Facts About AIDS (fact sheet): This fact sheet, in question and answer form, has been published every two to three months with basic information about AIDS, for use with all target audiences. Distribution usually amounts to 25,000 per month. In FY 1985, about six issues of the fact sheet are planned, with organizations, health care facilities, and others being encouraged to reproduce the fact sheet themselves. At least two of the issues will be translated into Spanish.

3. MMWR Selected Reprints: Several appropriate articles from the MMWR will be collected into one publication for distribution primarily to health care personnel on request. Experience has also shown the reprints to be of special interest to many persons in risk groups and to their families.

4. MMWR reprints of PHS-Recommended Precautions Regarding AIDS: Demand for this reprint has been at least 10,000 copies per month during 1984 among health care workers and families of AIDS patients and is expected to continue.

5. AIDS Hotline: Use of the AIDS hotline has varied from a high of about 5,000 calls per day to a low of 150 calls per day between July 1983 and July 1984, with the average expected to be maintained at about 200 during 1985. Initially, PHS staff

answered questions raised by callers, and a tape-recorded three minute audiotape with AIDS information was used 24 hours a day. Currently only the audiotape is used, except when a new development is announced or OPA is aware of a special promotion of the AIDS hotline number; then the tape is supplemented by a hotline operator to answer questions. Incoming lines will be reduced from 8 to 4.

6. Videotape Updates (trailers): Three videotapes were prepared in FY 1984 for use among the public, nurse and hospital lab workers, and emergency and correctional workers. These tapes are being promoted and distributed by the National Audiovisual Center. The 20-minute tapes will require updating as new AIDS findings occur. This can be accomplished by trailers of up to 10 minutes at the end of the existing tapes, eliminating the need for reshooting the entire tapes.

7. Videotape for Primary Care Physicians: NIAID has prepared a videotape for use by physicians and at hospital continuing education programs describing AIDS treatment and research. The tape was editied from a one-day seminar sponsored by the Institute and will be distributed through appropriate mailing lists, for duplication by recipients and return for reuse. A trailer may be produced for this tape, too.

8. AIDS Publications (Updates): Four publications have been purchased from a private publisher for use with the general public, gay and bisexual men, health workers, and Spanish language audiences. For FY 1985, these publications must be updated to reflect new AIDS developments, especially availability of the blood test. FY 1984 distribution has been in bulk to any organization or facility that could make effective use of the materials in reaching a target audience. FY 1985 quantities can be reduced and commercial (for profit) organizations or facilities will be limited in quantities that will be provided free. Instead, these facilities will be encouraged to purchase the low-cost materials directly from the publisher.

9. Drug Abuser Program: NIDA has reprinted AIDS materials and generated materials of its own for distribution to drug abuse treatment and counseling centers. Communities and centers in California and New York have also developed materials of their own. FY 1985 activities will include sharing materials possibly through the Conference of Mayors (see no. 11), and perhaps developing appropriate items such as training videotapes and other educational materials. The program will be aimed at center staffs, families of drug abusers, mothers, and so-called recreational drug users.

10. Mental Health Aspects of AIDS: NIMH has been conducting research on this issue, and during FY 1985 is expected to have developed sufficient information to release, in publication or audiovisual form, for use in educating appropriate health personnel about mental illness aspects of AIDS and the mental

health needs of AIDS patients, their families, and close friends. A publication lisiting model mental health programs for people with AIDS, other hotlines, community efforts, support networks and education programs will be produced for State and local officials and other organizations.

11. Conference of Mayors Project: A contract was awarded during FY 1984 to the U.S. Conference of Mayors to provide for the sharing of AIDS information and education experiences and materials among the nation's cities and communities. This channel will be used as a distribution channel for appropriate PHS-developed materials (e.g. drug abuse-related AIDS information) and for the identification of materials and programs that are most effective in bringing about AIDS risk reduction. The project may be expanded to provide risk reduction and blood test information through gay community groups. A project evaluating and documenting substantial behavioral changes among high risk group members may also be initiated.

12. Haitian-Related Activities: A contract was awarded in FY 1984 to a Haitian community organization in Miami to develop materials and conduct a health information and education campaign among Haitians in the Miami area with emphasis on AIDS information. FY 1985 activity will include updating of the previous year's information materials, distribution, and possible application to Haitian communities in other parts of the country.

13. Survey of Physician Knowledge: A FY 1984 survey of public knowledge showed that most Americans had a general understanding of AIDS being confined to specific risk groups. The survey also determined the effectiveness of PHS-distributed information material. FY 1985 activities will include a survey of physician knowledge about AIDS and their perception of required patient information, which will to provide guidance to OPA in ensuring the development of materials that are both adequate and necessary. This project will be conducted in cooperation with the AMA.

14. Other press materials: Press releases, background papers and statements, and similar materials, in addition to aiding the news media, are also useful in secondary distribution to various target audiences. Other suggested materials include 3 mailings to weekly newspapers by contractor as part of a features service, and an authoritative source material kit and contact list for health writers and editorial writers.

15. NIH Radio Programs: In FY 1984, the NIH produced two 15 minute radio programs on AIDS as special supplements to the NIH regularly produced interview programs on research topics. Three five minute programs were also excerpted from each of the longer programs, with 11 the shows then distributed on albums to about 400 radio stations who request the NIH programming. This successful project is being planned for updating and preparation again in FY 1985. Planned emphasis is on the availability and use of a blood test for HTLV-III antibodies.

Cost Estimates FY 1985
AIDS Projects and Activities

Blood test materials (fact sheets/cards)...........	$ 20,000	
Facts About AIDS (fact sheet) (6 issues)...........	5,000	
Facts About AIDS (Spanish) (2 issues)..............	500	
MMWR Selected Reprints (collection)................	3,000	
MMWR Reprint of AIDS Precautions...................	2,000	
AIDS Hotline (Code-a-Phone)........................	2,500	
Videotape Updates..................................	5,000	
Videotape for Morticians and pathologists..........	20,000	(1)
AIDS Publications (Updates)........................	22,500	
Drug Abuser Program................................	50,000	(2)
Mental Health Aspects of AIDS......................	10,000	(3)
Conference of Mayors Project.......................	200,000	(4)
Haitian-Related Activities.........................	5,000	
Survey of Physician Knowledge......................	10,000	
Other Press Materials..............................	15,000	
NIH Radio Programs.................................	2,500	
Mailing/Request Handling/Distribution..............	25,000	
Meetings/Travel....................................	2,000	
TOTAL (NEEDED FOR TAP) (OPA)	$120,000	

OTHER AGENCY FUNDING (1,2,3,4)

(1) NIH to fund
(2) NIDA to fund
(3) NIMH to fund
(4) CDC to fund

Appendix E.—A Partial List of Organizations Involved in AIDS Lobbying, Public Education, Prevention, or Social Services

East Coast

GLH/AIDS Project
P.O. Box 11013
Durham, NC
(919) 286-0079

Gay Men's Alliance of Hudson Valley
255 Grove St.
White Plains, NY 10601
(914) 997-5149

Long Island AIDS Project
SUNY Health Sciences
Stony Brook, NY 11794
(516) 444-2404

AIDS Task Force, Inc.
P.O. Box 3B/Bidwell
Buffalo, NY 14222
(716) 886-1275

AIDS Program, HCC, Inc.
50 Court St., Suite 1001
Brooklyn, NY 11201
(212) 855-7275

SouTier AIDS Task Force
P.O. Box 1492
Binghamton, NY 13902
(607) 723-6493

Central NY AIDS Task Force
P.O. Box 1682
Syracuse, NY 13201
(315) 475-2430

AIDS Rochester, Inc.
153 Liberty Poleway
Rochester, NY 14604
(716) 232-7181

Capitol District AIDS
332 Hudson Ave.
Albany, NY 12110
(518) 465-6094

Haitian Coalition on AIDS
255 Eastern Parkway
Brooklyn, NY 11238
(212) 783-2676

AIDS Task Force
CDGLF, Box 131
Albany, NY 12201
(518) 465-6094

Lambda Legal Defense and Education Fund
132 W. 43rd St.
New York, NY 10036
(212) 944-9488

Haitian Committee on AIDS
117 Harvard St.
Dorchester, MA 02124
(617) 436-2808

Fenway Health Community Center/AIDS Action Committee
16 Haviland St.
Boston, MA 02115
(617) 267-7573

Gay Men's Health Crisis, Inc.
Box 274, 132 W. 24th St.
New York, NY 10011
(212) 807-6664

AID Atlanta
1132 W. Peachtree, NW, #112
Atlanta, GA 30309
(404) 872-0600

Philadelphia AIDS Task Force
P.O. Box 7259
Philadelphia, PA 19101
(215) 232-8055

AIDS Educ. Program
5900 W. Junior Coll. Rd.
Key West, FL 33040

AIDS Education Fund
2335 18th St., N.W.
Washington, DC 20009
(202) 332-5939

AIDS Project New Haven
P.O. Box 7
New Haven, CT 06473
(203) 239-7881

Gay and Lesbian Alliance of Delaware
P.O. Box 9218
Wilmington, DE 19809
(302) 764-2208

AIDS Action Committee
P.O. Box 4073
Key West, FL 33041
(305) 294-5531, ext. 4797

Health Crisis Net.
1930 Bay Drive, #2
Normandy Isle, FL 33141
(305) 448-2882

HERO/Medical Arts Bldg.
Cathedral & Read, #819
Baltimore, MD 21201
(301) 955-3150

Gay Rights National Lobby AIDS Project
P.O. Box 1892
Washington, DC 20013
(202) 546-1801

The Bar Association for Human Rights for Greater New York
P.O. Box 1899
Grand Central Station
New York, NY 10163

United States Conference of Mayors
1620 I St., N.W.
Washington, DC
(202) 254-8718

National Gay Task Force
80 Fifth Ave.
New York, NY 10011
(212) 714-5800

AIDS Action Council
Federation of AIDS-Related Organizations
1115 1/2 Independence Ave., S.E.
Washington, DC 20003
(202) 547-3101/547-3102

Mayor's Interagency Task Force on AIDS
1025 Worth St., Rm. 604
New York, NY 10013
(212) 566-0484

AIDS Resource Center, Inc.
235 W. 18th St.
New York, NY 10011
(212) 206-1414

AIDS Medical Foundation
230 Park Ave., Rm. 1266
New York, NY 10169
(212) 949-7410

AIDS Network Group
Department of Social Work
Memorial Sloan-Kettering
1275 York Ave.
New York, NY 10021
(212) 794-7018

Haitian Community Health Project
391 Eastern Parkway
Brooklyn, NY 11213
(718) 773-1171

AIDS Institute
New York State Department of Health
8 E. 40th St., 3rd floor
New York, NY 10016
(212) 340-3388

Lesbian and Gay Concern Committee
National Association of Social Workers
110 W. 86th St.
New York, NY 10024 (212) 799-3298

West Coast

AIDS Team
P.O. Box 9773
Fresno, CA 93794
(209) 264-2436

Pacific Center AIDS Project
2712 Telegraph Ave.
Berkeley, CA 94705
(415) 548-8283

AIDS Education/Research Foundation
P.O. Box 14227
San Francisco, CA 94123
(415) 626-8784

SF People with AIDS
1040 Ashbury, #5
San Francisco, CA 94117
(415) 665-3787

Los Angeles AIDS Network
811 N. Coronado Terrace
Los Angeles, CA 90026
(213) 483-8574

AIDS InterFaith Network
890 Hayes St.
San Francisco, CA 94117
(415) 558-9644

American Association of Physicians for Human Rights
P.O. Box 14546
San Francisco, CA 94114
(415) 673-3189

Seattle AIDS Action Comm.
113 Summit Ave. E., #204
Seattle, WA 98104
(206) 323-1229

Northwest AIDS Foundation
P.O. Box 3449
Seattle, WA 98114
(206) 527-8770; 622-9650; 322-6698

Gay Men's Health Group
2353 Minor Ave. E.
Seattle, WA 98102
(206) 322-3919

Seattle Gay Clinic
P.O. Box 20066
Seattle, WA 98104
(206) 322-2873

Cascade AIDS Project
408 S.W. 2nd Ave., Rm. 403
Portland, OR 97204
(503) 223-8299 (10 a.m.-3 p.m.)

AIDS Hotline
P.O. Box 968
Santa Fe, NM 87504
(505) 827-3201

New Mexico Physicians for Human Rights
P.O. Box 1361
Espanola, NM 87532
(505) 753-2779/984-1217

AIDS Project/L.A.
937 N. Cole Ave., #3
Los Angeles, CA 90038
(213) 871-1284

SF AIDS Foundation
54 10th St.
San Francisco, CA 94104
(415) 864-4376

Diablo V. Community Center
1818 Colfax St.
Concord, CA 94520
(415) 827-2960

Gay & Lesbian Community Services of Orange County
12832 Garden Grove Blvd.
Garden Grove, CA 92643
(714) 534-0862

Southern California Physicians for Human Rights
7985 Santa Monica Blvd., #109
Los Angeles, CA 90032
(213) 658-6261

AIDS/Kaposi's Sarcoma Foundation
2115 J. St., #3
Sacramento, CA 95816
(916) 448-AIDS

San Diego AIDS Project
P.O. Box 81082
San Diego, CA 92138
(619) 294-2437

San Francisco AIDS Project
P.O. Box 14227
San Francisco, CA 94114
(415) 864-4376

Shanti Project
890 Hayes St.
San Francisco, CA 94117
(415) 558-9644

Bay Area Physicians for Human Rights
P.O. Box 14546
San Francisco, CA 94114
(415) 558-9353 (adm.) or 372-7321 (medical)

Berkeley Gay Men's Clinic
2339 Durrant Ave.
Berkeley, CA 94704
(415) 548-2570 or 848-9220

AIDS/KS Foundation/SC Co.
715 North 1st St.
San Jose, CA 95112
(408) 298-4238 (hotline, 12 noon-9 p.m. M-F)

Colorado AIDS Project/GLCC
1436 Lafayette St.
Denver, CO 80218
(303) 831-6268

Central United States

Oklahoma for Human Rights
4107 East 2nd Place
Oklahoma City, OK 74112

Health Guard Foundation
417 NW 9th St.
Oklahoma, OK 73102
(405) 235-5693

AIDS Committee
1627 West Rosewood
San Antonio, TX 78201
(512) 736-5216

Oaklawn AIDS Action Project
5811 Nash
Dallas, TX 75235
(214) 351-1502

AIDS Vol. of Cincinnati
P.O. Box 2615
Cincinnati, OH 45201
(513) 542-0493

St. Louis Task Force on AIDS
P.O. Box 2905
St. Louis, MO 63130
(312) 862-9800

AIDS Support Group
c/o 2309 Girard Ave. S.
Minneapolis, MN 55405

Wellness Networks, Inc.
P.O. Box 1046
Royal Oaks, MI 48068
(313) 876-3582

Howard Brown Memorial Clinic/AIDS Action Project
2676 N. Halsted St.
Chicago, IL 60614
(312) 871-5777

Kaposi's Sarcoma/AIDS Foundation
3317 Montrose, Box 1155
Houston, TX 77006
(713) 524-2437

National Coalition of Gay Sexually Transmitted Disease Services
P.O. Box 239
Milwaukee, WI 53201
(414) 277-7671

LGCS/MN AIDS Project
124 West Lake St.
Minneapolis, MN 55408
(612) 827-2821

AIDS Task Force
P.O. Box 190712
Dallas, TX 75219
(214) 528-4233

AIDS Task Force
1022 Barracks St.
New Orleans, LA 70116
(504) 568-9619/524-7023

Appendix F.—Glossary of Acronyms and Terms

Glossary of Acronyms

ADAMHA—Alcohol, Drug Abuse, and Mental Health Administration (part of PHS)
AIDS—acquired immunodeficiency syndrome
ARV—AIDS-related virus
CDC—Centers for Disease Control (part of PHS)
DBDR—Division of Blood Diseases and Resources (part of NHLBI)
DHHS—Department of Health and Human Services
DNA—deoxyribonucleic acid
DRR—Division of Research Resources (part of NIH)
FDA—Food and Drug Administration (part of PHS)
FOCMA—feline-oncornavirus-cell-membrane-associated antigen
FTEs—full-time equivalents
HPA-23—heteropolytungstate
HRSA—Health Resources and Services Administration (part of PHS)
HTLV-I—human T-cell lymphotropic virus, type I
HTLV-II—human T-cell lymphotropic virus, type II
HTLV-III—human T-cell lymphotropic virus, type III
IDAV—immune-deficiency-associated virus
LAV—lymphadenopathy-associated virus
MCHBG—Maternal and Child Health Block Grants
NCI—National Cancer Institute (part of NIH)
NEI—National Eye Institute (part of NIH)
NHLBI—National Heart, Lung, and Blood Institute (part of NIH)
NIAID—National Institute of Allergy and Infectious Diseases (part of NIH)
NIDA—National Institute on Drug Abuse (part of ADAMHA)
NIDR—National Institute of Dental Research (part of NIH)
NIH—National Institutes of Health (part of PHS)
NIMH—National Institute of Mental Health (part of ADAMHA)
NINCDS—National Institute of Neurological and Communicative Disorders and Stroke (part of NIH)
OASH—Office of the Assistant Secretary for Health (part of PHS)
OMB—Office of Management and Budget (part of Executive Office of the President)
OPA—Office of Public Affairs (part of OASH)
OPRR—Office of Protection from Research Risks (part of NIH)
OTA—Office of Technology Assessment (part of U.S. Congress)
PHS—Public Health Service (part of DHHS)
RFAs—requests for applications
RNA—ribonucleic acid
TCGF—T-cell growth factor (also known as interleukin-2)

Glossary of Terms

Acquired immunodeficiency syndrome (or acquired immune deficiency syndrome): See "AIDS."

Active immunity: Protection against a disease resulting from the production of antibodies in a host (i.e., person or animal) that has been inoculated with an antigen. (Compare "passive immunity.")

Adenoviruses: Any of a group of DNA-containing viruses originally identified in human adenoid tissue, causing respiratory diseases, and including some capable of inducing malignant tumors in experimental animals. (See also "viruses" and compare "reoviruses" and "retroviruses.")

AIDS (acquired immunodeficiency syndrome): A disease believed to be caused by the retrovirus HTLV-III (human T-cell lymphotropic virus, type III) and characterized by a deficiency of the immune system. The primary defect in AIDS is an acquired, persistent, quantitative functional depression within the T4 subset of lymphocytes. This depression often leads to infections caused by micro-organisms that usually do not produce infections in individuals with normal immunity or to the development of a rare type of cancer (Kaposi's sarcoma) usually seen in elderly persons or in individuals who are severely immunocompromised from other causes. Other associated diseases are currently under investigation and will probably be included in the final definition of AIDS.

AIDS-related complex: A variety of chronic but nonspecific symptoms and physical findings that appear related to AIDS, which may consist of chronic generalized lymphadenopathy, recurrent fevers, weight loss, minor alterations in the immune system, and minor infections. Some persons with AIDS-related complex may develop full-blown AIDS, while in others, the condition may represent the height of clinical illness in reaction to infection with HTLV-III. AIDS-related complex is sometimes known as "pre-AIDS." (Compare "lymphadenopathy syndrome.")

Antibody: A blood protein produced by mammals in response to exposure to a specific antigen. Antibodies are a critical component of the mammalian immune system.

Antigen: A large molecule, usually a protein or carbohydrate, which when introduced into the body stimulates the production of an antibody that will react specifically with that antigen.

Appropriation: An act of Congress that authorizes one or more Federal agencies to incur "obligations" (see definition below) and make payments from the general fund or various special funds of the U.S. Treasury. Appropriations do not represent funds available in the Treasury, but are limitations on the amounts that agencies may obligate during the time period stated in the law.

ARV (AIDS-related retrovirus): A retrovirus recovered from an AIDS patient and believed to be the same virus as HTLV-III. (See "HTLV-III.")

B lymphocytes (or B cells): Lymphocytes that mediate humoral (e.g., antibody production) immune reactions. B lymphocytes proliferate under stimulation from factors released by T lymphocytes. (Compare "T lymphocytes.")

Budget authority: Funds that are appropriated by Congress for obligated purposes, or less commonly, requests to Congress for such appropriations.

Clone: A group of genetically identical cells or organisms produced asexually from a common ancestor.

Cofactor: Factors or agents which are necessary or which increase the probability of the development of disease in the presence of the basic etiologic agent of that disease.

Core proteins: Proteins that make up the internal structure or core of a virus. (Compare "envelope proteins.")

Cytopathic: Pertaining to or characterized by abnormal changes in cells.

Cytotoxic: Poisonous to cells.

DNA (deoxyribonucleic acid): A linear polymer, made up of deoxyribonucleotide repeating units, that is the carrier of genetic information in living organisms. Recombinant DNA is a hybrid DNA formed by joining pieces of DNA from different organisms in vitro.

Envelope proteins: Proteins that comprise the envelope or surface of a virus. (Compare "core proteins.")

Enzyme: Any of a group of catalytic proteins that are produced by living cells and that mediate and promote the chemical processes of life without themselves being altered or destroyed.

Epidemiologic studies: Studies concerned with the relationships of various factors determining the frequency and distribution of specific diseases in a human community.

Etiologic agent: Causative agent.

Expenditures: Amounts actually expended by Federal agencies as a result of obligations. (Compare "obligations.")

Factor VIII: A naturally occurring protein in plasma that aids in the coagulation of blood. A congenital deficiency of Factor VIII results in the bleeding disorder known as hemophilia A.

Factor VIII concentrate: A concentrated preparation of Factor VIII that is used in the treatment of individuals with hemophilia A.

Fulminant: Severe.

Gene: The basic unit of heredity; an ordered sequence of nucleotide bases, comprising a segment of DNA. A gene contains the sequence of DNA that encodes for the synthesis of one polypeptide chain (protein).

Gene expression: The mechanisms through which directions contained within the genes that code for a cell's products are transferred and used to direct the production process. (See also "transcription" and "translation.")

Genome: The genetic endowment of an organism.

Glycoproteins: Proteins with carbohydrate groups attached at specific locations.

Glycosylation: The attachment of a carbohydrate molecule to another molecule such as a protein.

Hemophilia: A rare, hereditary bleeding disorder caused by a deficiency in the ability to synthesize one or more of the blood coagulation proteins, e.g., Factor VIII (hemophilia A) or Factor IX (hemophilia B).

Hepatitis: Inflammation of the liver; may be due to many causes, including viruses, several of which are transmissible through blood transfusions.

HPA-23 (heteropolytungstate): A drug which has been shown to inhibit the reverse transcriptase enzyme of murine (mouse) retrovirus in vitro and in vivo, and which has been shown in early clinical trials to inhibit HTLV-III replication in humans, but which has not eradicated the virus. (Compare "ribavirin" and "suramin.")

HTLV-III (human T-cell lymphotropic virus, type III): A newly discovered retrovirus that is believed to be the basic cause of AIDs. The target organ of

HTLV-III is the T4 subset of T lymphocytes, which are the master regulators of the immune system. (In this memorandum, HTLV-III is used to refer to the various isolates (e.g., IDAV, LAV, ARV) that have been associated with AIDS.)

IDAV (immune-deficiency-associated virus): A retrovirus recovered from an AIDS patient and now believed to be the same virus as HTLV-III. (See "HTLV-III.")

Idiotype (or idiotope): A site on the variable portion (combining site) of an antibody molecule that can be recognized by a combining site of other antibodies.

Immune: Being highly resistant to a disease because of the formation of humoral antibodies or the development of cellular immunity, or both, or as a result of some other mechanism (e.g., interferon activity in viral infections). (See also "active immunity" and "passive immunity.")

Interferon: A class of glycoproteins (proteins with carbohydrates attached at specific locations) important in immune function and thought to inhibit viral infections.

In vitro: Literally, "in glass"; pertaining to a biological reaction taking place in an artificial apparatus; often used in reference to the growth of cells from multicellular organisms under cell culture conditions.

In vivo: Literally, "in the living"; pertaining to a biological reaction taking place in a living organism.

Kaposi's sarcoma: A multifocal, spreading cancer of connective tissue, principally involving the skin; it usually begins on the toes or the feet as reddish blue or brownish soft nodules and tumors.

LAV (lymphadenopathy-associated virus): A retrovirus recovered from a person with lymphadenopathy (enlarged lymph nodes) who was also in a group at high risk for AIDS, and now believed to be the same virus as HTLV-III. (See "HTLV-III.")

Lymphadenopathy: Enlargement of the lymph nodes.

Lymphadenopathy syndrome (LAS): A condition which is characterized by persistent, generalized, enlarged lymph nodes, sometimes with signs of minor illness such as fever and weight loss, which apparently represents a milder reaction to infection with HTLV-III than full-blown AIDS. Some patients with LAS have gone on to develop full-blown AIDS, while in others, LAS may represent the height of clinical illness in reaction to infection with HTLV-III. LAS is also known as "generalized lymphadenopathy syndrome." (Compare "AIDS-related complex.")

Lymphocytes: Specialized white blood cells involved in the immune response. (See also "B lymphocytes" and "T lymphocytes.")

Lymphosarcoma: A general term applied to malignant neoplastic disorders of lymphoid tissue, but not including Hodgkin's disease.

Messenger RNA (mRNA): RNA that serves as the template for protein synthesis; it carries the transcribed genetic code from the DNA to the protein synthesizing complex to direct protein synthesis. (See also "RNA.")

Monoclonal antibodies: Homogeneous antibodies derived from clones of a single cell. Monoclonal antibodies recognize only one chemical structure and thus have remarkable specificity. They are easily produced in large quantities and have a variety of medical and industrial uses.

Obligations: Amounts stipulated in contractual agreements between the Federal Government and other parties. (Compare "expenditures.")

Opportunistic infection: A disease or infection caused by a micro-organism that does not ordinarily cause disease but which, under certain conditions (e.g., impaired immune responses), becomes pathologic.

Passive immunity: Disease resistance in a person or animal due to the injection of antibodies from another person or animal. Passive immunity is usually short-lasting. (Compare "active immunity.")

***Pneumocystis carinii* pneumonia:** A type of pneumonia primarily found in infants and now commonly occurring in patients with AIDS.

Post-translational modification: The process by which the protein product of gene expression is modified, such as through attachment of carbohydrate groups. (See also "gene expression," "translation," and "glycosylation.")

Provirus: The genome of an animal virus integrated into the chromosome of the host cell, and thereby replicated in all of the host's daughter cells.

Recombinant DNA techniques: Techniques that allow specific segments of DNA to be isolated and inserted into a bacterium or other host (e.g., yeast, mammalian cells) in a form that will allow the DNA segment to be replicated and expressed as the cellular host multiplies. The DNA segment is said to be "cloned" because it exists free of the rest of the DNA of the organism from which it was derived.

Reoviruses: Any of a group of relatively large, widely distributed, and possibly tumor-causing viruses with double-stranded RNA. Unlike retroviruses, which also contain RNA, reoviruses replicate in the cytoplasm of the cells they invade and do not produce DNA analogs to their RNA for incorporation into the host cell's genome. (See also "viruses" and compare "adenoviruses" and "retroviruses.")

Retroviruses: Viruses that contain RNA, not DNA, and that produce a DNA analog of their RNA through the production of an enzyme known as "reverse transcriptase." The resulting DNA is incorporated in the genetic structure of the invaded cell in a form referred to as the "provirus." (See also "provirus" and "viruses" and compare "adenoviruses" and "reoviruses.")

Reverse transcriptase: An enzyme produced by retroviruses that allows them to produce a DNA analog of their RNA, which is then incorporated into the host cell. (See also "retroviruses.")

Ribavirin: A drug which has been shown to protect T4 cells against infection by HTLV-III in vitro, and which is being tested in AIDS patients. (Compare "suramin" and "HPA-23.")

RNA (ribonucleic acid): Any of various nucleic acids that contain ribose and uracil as structural components and are associated with the control of cellular chemical activities. (See also "messenger RNA.")

Serum: The clear portion of any animal liquid separated from its more solid elements, especially the clear liquid (blood serum) which separates in the clotting of blood.

Subunit vaccine: A vaccine that contains only portions of a surface molecule of a pathogen. (See also "vaccine.")

Suramin: A drug that has been shown to protect T4 cells against infection by HTLV-III in vitro, and which is being tested in AIDS patients. (Compare "ribavirin" and "HPA-23.")

T-cell growth factor (TCGF, also known as interleukin-2): A glycoprotein that is released by T lymphocytes on stimulation with antigens and which functions as a T-cell growth factor by inducing proliferation of activated T cells. (See also "T lymphocytes" and "glycoproteins.")

T lymphocytes (or T cells): Lymphocytes that mature in the thymus and which mediate cellular immune reactions. T lymphocytes also release factors that induce proliferation of T lymphocytes and B lymphocytes. (Compare "B lymphocytes.")

Transcription: The synthesis of messenger RNA on a DNA template; the resulting RNA sequence is complementary to the DNA sequence. This is the first step in gene expression. (See also "gene expression" and compare "translation.")

Transfer authority: Authority from Congress to transfer money from one appropriation to another within an agency or across agencies.

Translation: The process in which the genetic code contained in the nucleotide base sequence of messenger RNA directs the synthesis of a specific order of amino acids to produce a protein. (See also "gene expression" and compare "transcription.")

Tropism: An innate tendency to react in a definite manner to stimuli.

Vaccine: A preparation of killed organisms, living attenuated organisms, living fully virulent organisms, or parts of micro-organisms, that is administered to produce or artificially increase immunity to a particular disease.

Viruses: Any of a large group of submicroscopic agents capable of infecting plants, animals, and bacteria, and characterized by a total dependence on living cells for reproduction and by a lack of independent metabolism. (See also "adenoviruses," "provirus," "reoviruses," and "retroviruses.")

References

References

1. Alizon, M., Sonigo, P., Barre-Sinoussi, F., et al., "Molecular Cloning of Lymphadenopathy-Associated Virus," *Nature* 312:757-760, Dec. 20/27, 1984.
2. Alter, H.J., Eichberg, J.W., Masur, H., et al., "Transmission of HTLV-III Infection From Human Plasma to Chimpanzees: An Animal Model for AIDS," *Science* 226:549-552, Nov. 2, 1984.
3. American Association of Blood Banks, "HTLV-III Kits To Proceed Despite Unanswered Questions," *AABB Newsbriefs* 7(11):1, 8-9, November/December 1984.
4. American Association of Blood Banks, "Anti-HTLV-III Testing: A Statement From the American Association of Blood Banks," Arlington, VA, Dec. 27, 1984.
5. American Blood Commission and The Hastings Center, "Policy Conference on AIDS, Ethics, and the Blood Supply," Arlington, VA, Jan. 29-30, 1985.
6. Aoki, T., Miyakoshi, H., Usuda, Y., et al., "Antibodies to HTLV I and III in Sera From Two Japanese Patients, One With Possible Pre-AIDS" (letter), *Lancet* 2:936-937, Oct. 20, 1984.
7. Barre-Sinoussi, F., Chermann, J.C., Rey, F., et al., "Isolation of a T-Lymphotropic Retrovirus From a Patient at Risk for Acquired Immune Deficiency Syndrome (AIDS)," *Science* 220:868-871, May 30, 1983.
8. Batchelor, W.F., "AIDS: A Public Health and Psychological Emergency," *Am. Psychologist* 39:1279-1284, November 1984.
9. Bayer, H., Bienzle, U., Schneider, J., et al., "HTLV-III Antibody Frequency and Severity of Lymphadenopathy," *Lancet* 2:1347-1348, Dec. 8, 1984.
10. Bayer, R., Levine, C., and Murray, T., "Guidelines for Confidentiality in Research on AIDS," *IRB: A Review of Human Subjects Research* 6(6):1-7, November/December 1984.
11. Behan, W.M.H., and Burt, A.D., "HTLV-III Seropositivity in AIDS" (letter), *Lancet* 2:1292, June 9, 1984.
12. Biggar, R.J., Melbye, M., Kestems, L., et al., "Kaposi's Sarcoma in Zaire Is Not Associated With HTLV-III Infection" (letter), *N. Engl. J. Med.* 311:1051, Oct. 18, 1984.
13. Biogen, Inc., "Biogen Licenses Hepatitis B Vaccine," press release, Cambridge, MA, Oct. 10, 1984.
14. *Biomedical Business International*, VII(120/121): 191, Nov. 5, 1984) (a newsletter based in Tustin, CA).
15. Biviano, J., Budget Analyst, Food and Drug Administration, Rockville, MD, personal communication, Aug. 28, 1984.
16. Blattner, W., National Cancer Institute, National Institutes of Health, Bethesda, MD, personal communication, Oct. 9, 1984.
17. Boggan, E.C., Haft, M.G., Lister, C., et al., *The Rights of Gay People* (An American Civil Liberties Union Handbook) (New York: Bantam Books, 1983).
18. Brandt, E.N., Jr., Assistant Secretary for Health, Public Health Service, U.S. Department of Health and Human Services, "Executive Task Force on AIDS," memorandum to PHS Agency Heads, May 7, 1984.
19. Brandt, E.N., Jr., Assistant Secretary for Health, Public Health Service, U.S. Department of Health and Human Services, letter to Congressman William Natcher, Chairman, Subcommittee on Labor, Health, and Human Services, Committee on Appropriations, U.S. House of Representatives, May 18, 1983 (citation from U.S. Congress, House Committee on Government Operations, *The Federal Response to AIDS*, 1983).
20. Brandt, E.N., Jr., Assistant Secretary for Health, Public Health Service, U.S. Department of Health and Human Services, "Proposed FY 1984 Supplemental and FY 1985 Amendment for Acquired Immunodeficiency Syndrome," memorandum to the Secretary of Health and Human Services, May 25, 1984.
21. Brandt, E.N., Jr., Assistant Secretary for Health, Public Health Service, U.S. Department of Health and Human Services, statement before the Subcommittee on Health and the Environment, Committee on Energy and Commerce, U.S. House of Representatives, Washington, DC, Sept. 17, 1984.
22. Brandt, E.N., Jr., Assistant Secretary for Health, Public Health Service, U.S. Department of Health and Human Services, letter to Office of Technology Assessment, U.S. Congress, Dec. 20, 1984.
23. Broder, S., and Gallo, R.C., "A Pathogenic Retrovirus (HTLV-III) Linked to AIDS," *N. Engl. J. Med.* 311:1292-1297, Nov. 15, 1984.
24. Brody, H., and Lynn, J., "The Physician's

Responsibility Under the New Medicare Reimbursement for Hospice Care," *N. Engl. J. Med.* 310:920-922, Apr. 5, 1984.

25. Brun-Vezinet, F., Barre-Sinoussi, F., Saimot, A.G., et al., "Detection of IgG Antibodies to Lymphadenopathy-Associated Virus in Patients With AIDS or Lymphadenopathy Syndrome," *Lancet* 1:1253-1256, June 9, 1984.
26. Brun-Vezinet, F., Rouzioux, C., Montagnier, L., et al., "Prevalence of Antibodies to Lymphadenopathy-Associated Retrovirus in African Patients With AIDS," *Science* 226:453-456, Oct. 26, 1984.
27. Buimovici-Klein, E., Lange, M., Ramey, W.G., et al., "Cell-Mediated Immune Responses in AIDS" (letter), *N. Engl. J. Med.* 311:328, Aug. 2, 1984.
28. Cabane, J., Thibierge, F., Godeau, P., et al., "AIDS in an Apparently Risk-Free Woman" (letter), *Lancet* 2:105, July 14, 1984.
29. Chabner, B., Director, Division of Cancer Treatment, National Cancer Institute, National Institutes of Health, Bethesda, MD, personal communication, Sept. 14, 1984.
30. Chalmer, B., Director, Division of Cancer Treatment, National Cancer Institute, National Institutes of Health, Bethesda, MD, personal communication, Sept. 14, 1984.
31. Check, W.A. "AIDS/HTLV Story Raises Troublesome Issues," *SW: The Newsletter of the National Association of ScienceWriters* 32:1-6, July 1984.
32. Cheingsong-Popov, R., Weiss, R.A., Dalgleish, A., et al., "Prevalence of Antibody to Human T-Lymphotropic Virus Type III in AIDS and AIDS-Risk Patients in Britain," *Lancet* 2:477-483, Sept. 1, 1984.
33. Chernoff, A., Division of Blood Diseases and Resources, National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, MD, personal communication, Sept. 20, 1984.
34. Clumeck, N., Sonnet, J., Taelman, H., et al., "Acquired Immunodeficiency Syndrome in African Patients," *N. Engl. J. Med.* 310:492-497, Feb. 23, 1984.
35. Coates, T.J., Temoshok, L., and Mandel, J., "Psychosocial Research Is Essential to Understanding and Treating AIDS," *Am. Psychologist* 39:1309-1314, November 1984.
36. Cooper, A., "The High Stakes Race Is On To Develop Blood Test To Detect AIDS Virus," *Natl. J.* 16:1470-1472, Aug. 4, 1984.
37. Culliton, B.J., "Crash Development of AIDS Test Nears Goal," *Science* 225:1128-1131, Sept. 4, 1984.
38. Curran, J., Centers for Disease Control, Atlanta, GA, personal communications, Aug., 9, 1984; Nov. 6, 1984; Jan. 10, 1985.
39. Dalgleish, A.G., Beverley, P.C.L., Clapham, P.R., et al., "The CD4 (T4) Antigen is an Essential Component of the Receptor for the AIDS Retrovirus," *Nature* 312:763-767, Dec. 20/27, 1984.
40. Dodd, R., American National Red Cross, Bethesda, MD, personal communication, Dec. 6, 1984.
41. duBuy, Y., Financial Management Section, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD, personal communications, Nov. 6, 1984; Dec. 28, 1984.
42. Evatt, B., Centers for Disease Control, Atlanta, GA, personal communication, Sept. 12, 1984.
43. Evatt, B., et al., "Appearance of Antibody to LAV in Hemophiliacs Coincident With the AIDS Epidemic," *N. Engl. J. Med.* (in press).
44. Fanton, R., Norden Laboratories, Lincoln, NE, personal communication, Nov. 21, 1984.
45. Fahey, J.L., Prince, H., Weaver, M., et al., "Quantitative Changes in T Helper or T Suppressor/Cytotoxic Lymphocyte Subsets That Distinguish Acquired Immune Deficiency Syndrome From Other Immune Subset Disorders," *Am. J. Med.* 76:95-100, January 1984.
46. Fauci, A., National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD, personal communication, Oct. 4, 1984.
47. Feorino, P.M., Kalyanaraman, V.S., Haverkos, H.W., et al., "Lymphadenopathy Associated Virus Infection of a Blood Donor-Recipient Pair With Acquired Immunodeficiency Syndrome," *Science* 225:69-72, July 6, 1984.
48. Fischinger, P., Associate Director, National Cancer Institute, National Institutes of Health, Bethesda, MD, personal communications, Oct. 12, 1984; Nov. 6, 1984; Dec. 11, 1984; Jan. 3, 1985.
49. Flaherty, F.J., "A Legal Emergency Brewing Over AIDS," *Natl. Law J.* 6(44):1, July 9, 1984.
50. Forbush, W., Office of Management, Public Health Service, U.S. Department of Health and Human Services, Washington, DC, personal communication, Sept. 7, 1984.

51. Francis, D., Centers for Disease Control, Atlanta, GA, personal communication, Sept. 12, 1984.
52. Francis, D.P., Feorino, P.M., Broderson, J.R., "Infection of Chimpanzees With Lymphadenopathy-Associated Virus" (letter), *Lancet* 2:1276-1277, Dec. 1, 1984.
53. Gajdusek, D., Amyx, H., Gibbs, C., Jr., et al., "Transmission Experiments With Human T-Lymphotropic Retroviruses and Human AIDS Tissue," *Lancet* 1:1415-1416, June 23, 1984.
54. Gajdusek, D., Gibbs, C., Jr., Rodgers-Johnson, P., et al., "Infection of Chimpanzees by Human T-Lymphotropic Retroviruses in Brain and Other Tissues From AIDS Patients," *Lancet* 1:55-56, Jan. 5, 1985.
55. Galasso, G., Office of the Director, National Institutes of Health, Bethesda, MD, personal communication, Sept. 21, 1984.
56. Gallo, R.C., National Cancer Institute, National Institutes of Health, Bethesda, MD, personal communication, Sept. 6, 1984.
57. Gallo, R.C., Salahuddin, S.Z., Popovic, M., et al., "Frequent Detection and Isolation of Cytopathic Retroviruses (HTLV-III) From Patients With AIDS and at Risk for AIDS," *Science* 224:500-502, May 4, 1984.
58. Gazzard, B.G., Farthing, C., Shanson, D.C., et al., "Clinical Findings and Serological Evidence of HTLV-III Infection in Homosexual Contacts of Patients With AIDS and Persistent Generalised Lymphadenopathy in London," *Lancet* 2:480-483, Sept. 1, 1984.
59. Gazzolo, L., Gessain, A., Carrel, A., et al., "Antibodies to HTLV-III in Haitian Immigrants in French Guiana" (letter), *N. Engl. J. Med.* 311: 1252-1253, Nov. 8, 1984.
60. Goedert, J.J., Sarngadharan, M.G., Eyster, M.E., et al., "Antibodies Reactive With Human T-Cell Leukemia Viruses in the Serum of Hemophiliacs Receiving Factor VIII Concentrate," *Blood* 65:492-495, February 1985.
61. Goedert, J.J., Biggar, R.J., Winn, D.M., et al., "Determinants of Retrovirus (HTLV-III) Antibody and Immunodeficiency Conditions in Homosexual Men," *Lancet* 2:711-715, Sept. 29, 1984.
62. Ginzburg, H., "HTLV Infection in Intravenous Drug Abusers," presented at the HTLV Symposium, sponsored by the National Cancer Institute, National Institutes of Health, Bethesda, MD, Dec. 6 and 7, 1984.
63. Gonda, M.A., Wong-Staal, F., Gallo, R.C., et al., "Sequence Homology and Morphologic Similarity of HTLV-III and Visna Virus, a Pathogenic Lentivirus," *Science* 227:173-177, Jan. 11, 1985.
64. Gonzales, M., Public Health Service, U.S. Department of Health and Human Services, Washington, DC, personal communication, Nov. 8, 1984.
65. Groopman, J.E., Salahuddin, S.Z., Sarngadharan, M.G., et al., "HTLV-III in Saliva of People With AIDS-Related Complex and Healthy Homosexual Men at Risk for AIDS," *Science* 226:447-448, Oct. 26, 1984.

65a. Gyorkey, F., Melnick, J.L., Sinkovics, J.G., et al., "Retrovirus Resembling HTLV in Macrophages of Patients With AIDS," *Lancet* 1:106, Jan. 12, 1985.

66. Hahn, B.H., Shaw, G.M., Arya, S.K., et al., "Molecular Cloning and Characterization of the HTLV-III Virus Associated With AIDS," *Nature* 312:166-169, November 1984.
67. Hardy, A.M., Allen, J.R., Morgan, W.M., et al., "The Incidence Rate of Acquired Immunodeficiency Syndrome in Selected Populations," *J.A.M.A.* 253:215-220, Jan. 11, 1985.
68. Harper, M., Wong-Staal, F., Gallo, R., et al., "Detection of HTLV-III-Infected Lymphocytes in AIDS Patients Using a Highly Sensitive *in situ* Hybridization Method" (manuscript in preparation).
69. Harvey Milk Lesbian and Gay Democratic Club, "Can We Talk" (brochure), San Francisco, CA, 1984.
70. Heckler, M.M., Secretary, U.S. Department of Health and Human Services, Washington, DC, "FY 1984 AIDS Requirements," memorandum to Dr. E.N. Brandt, Jr., Assistant Secretary for Health, Public Health Service, Aug. 8, 1984.

70a. Heckler, M.M., Secretary, U.S. Department of Health and Human Services, Washington, DC, statement regarding AIDS, Apr. 23, 1984.

71. Hehlmann, R., Kreeb, G., Erfle, V., et al., "Antibodies to HTLV-III in Patients With Acquired Immunodeficiency or Lymphadenopathy Syndrome in West Germany" (letter), *Lancet* 2:1094, Nov. 10, 1984.
72. Hirsch, M.S., Wormser, G.P., Schooley, R.T., et al., "Risk of Nosocomial Infection With Human T-Cell Lymphotropic Virus III (HTLV-III)," *N. Engl. J. Med.* 312:1-4, Jan. 3, 1985.
73. Ho, D.D., Schooley, R.T., Rota, T.R., et al., "HTLV-III in the Semen and Blood of a Healthy Homosexual Man," *Science* 226:451-453, Oct. 26, 1984.
74. Hunsmann, G., remarks made during a discussion of vaccines for HTLV viruses at the HTLV Symposium, sponsored by the National Cancer

Institute, National Institutes of Health, Bethesda, MD, Dec. 6 and 7, 1984.

75. Johnson, R., Staff Associate, U.S. Conference of Mayors, Washington, DC, personal communication, Jan. 15, 1985.

76. Joseph, J.G., Emmons, C-A., Kessler, R.C., et al., "Coping With the Threat of AIDS: An Approach to Psychosocial Assessment," *Am. Psychologist* 39(11):1297-1302, November 1984.

77. Kalyanaraman, V.S., Cabradilla, C.D., Getchell, J.P., et al., "Antibodies to the Core Protein of Lymphadenopathy-Associated Virus (LAV) in Patients With AIDS," *Science* 225:321-323, July 20, 1984.

78. Kieny, M.P., Lathe, R., Drillien, R., et al., "Expression of Rabies Virus Glycoprotein From a Recombinant Vaccinia Virus," *Nature* 312:163-166, Nov. 8, 1984.

79. Kitchen, L.W., Barin, F., Sullivan, J.L., et al., "Aetiology of AIDS—Antibodies to Human T-Cell Leukaemia Virus (Type III) in Haemophiliacs" (letter), *Nature* 312:367-369, Nov. 22/28, 1984.

80. Klatzmann, D., Barre-Sinoussi, F., Nugeyre, M.T., et al., "Selective Tropism of Lymphadenopathy Associated Virus (LAV) for Helper-Inducer T Lymphocytes," *Science* 225:59-63, July 6, 1984.

81. Klatzmann, D., Champagne, E., Chamaret, S., et al., "T-Lymphocyte T4 Molecule Behaves as the Receptor for Human Retrovirus LAV," *Nature* 312:767-768, Dec. 20/27, 1984.

82. Kreuter, M., Centers for Disease Control, Atlanta, GA, personal communication, Sept. 13, 1984.

83. Lambda Legal Defense and Education Fund, *AIDS Legal Guide: A Professional Resource on AIDS-related Issues and Discrimination* (New York: Lambda Legal Defense and Education Fund, 1984).

84. Lane, H.C., "Management of AIDS," presented at the HTLV Symposium, sponsored by the National Cancer Institute, National Institutes of Health, Bethesda, MD, Dec. 6 and 7, 1984.

85. Lane, H.C., Masur, G., Longo, D.L., et al., "Partial Immune Reconstitution in a Patient With the Acquired Immunodeficiency Syndrome," *N. Engl. J. Med.* 311:1099-1103, Oct. 25, 1984.

86. Laurence, J., Brun-Vezinet, F., Schutzer, S.E., et al., "Lymphadenopathy-Associated Viral Antibody in AIDS, Immune Correlations and Definition of a Carrier State," *N. Engl. J. Med.* 311:1269-1273, Nov. 15, 1984.

87. Lengel, S.J., Director, Office of Public Affairs, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services, Washington, DC, personal communication, Aug. 9, 1984.

88. Levi, J., representative of the National Gay Task Force, Washington, DC, personal communication, Dec. 10, 1984.

89. Levy, J., Hoffman, A.D., Kramer, S.M., et al., "Isolation of Lymphocytopathic Retroviruses From San Francisco Patients With AIDS," *Science* 225:840-842, Aug. 24, 1984.

90. Little, W.H., Office of the Assistant Secretary for Health, Public Health Service, U.S. Department of Health and Human Services, Rockville, MD/Washington, DC, personal communications, Oct. 26, 1984; Dec. 28, 1984.

91. Luciw, P.A., Potter, S.J., Steimer, K., et al., "Molecular Cloning of AIDS-Associated Retrovirus," *Nature* 312:760-763, Dec. 20/27, 1984.

92. MacDonald, G.B., Executive Director, AIDS Action Council, Washington, DC, personal communication, Dec. 10, 1984.

93. Manley, A., Associate Administrator for Clinical Affairs, Health Resources and Services Administration, U.S. Department of Health and Human Services, Rockville, MD, personal communication, Sept. 19, 1984.

94. Mansfield, N.D., Division of Financial Management, National Institutes of Health, Bethesda, MD, letter to Office of Technology Assessment, U.S. Congress, Oct. 22, 1984.

95. Martin, J.L., and Vance, C.S., "Behavioral and Psychosocial Factors in AIDS: Methodological and Substantive Issues," *Am. Psychologist* 39:1303-1308, November 1984.

96. Mason, J., Director, Centers for Disease Control, Atlanta, GA, personal communication, Jan. 15, 1985.

97. Mathez, D., Leibowitch, J., Catalan, P., et al., "HTLV and AIDS in France" (letter), *Lancet* 1:799, Apr. 7, 1984.

98. McCarthy, C., Dommel, W., and McKay, C., Office of Protection From Research Risks, Office of the Director, National Institutes of Health, Bethesda, MD, personal communication, Aug. 30, 1984.

99. McCormick, J.B., Mitchell, S.W., Getchell, J.P., et al., "Ribavirin Suppresses Replication of Lymphadenopathy-Associated Virus in Cultures of Human Adult T Lymphocytes," *Lancet* 2:1367-1369, Dec. 15, 1984.

99a. McKusick, L., Project Director, AIDS Behavioral Research Project, University of California, San Francisco, personal communication, Dec. 11, 1984.

100. McNamara, M.K., Ward, R.E., and Kohler, H., "Monoclonal Idiotope Vaccine Against *Streptococcus pneumoniae* Infection," *Science* 226: 1325-1326, Dec. 14, 1984.

101. Medical World News, "FDA Advisory Committee Calls for Thorough Testing of Recombinant Vaccines," *Medical World News* 25(14):28-29, July 23, 1984.

102. Medical World News, "Progress on AIDS," *Medical World News* 25(21):30-32, Nov. 12, 1984.

103. Melbye, M., Biggar, R.J., Chermann, J.C., et al., "High Prevalence of Lymphadenopathy Virus (LAV) in European Haemophiliacs" (letter), *Lancet* 2:40-41, July 7, 1984.

104. Melbye, M., Biggar, R.J., Ebbesen, P., et al., "Seroepidemiology of HTLV-III Antibody in Danish Homosexual Men: Prevalence, Transmission, and Disease Outcome," *Br. Med. J.* 289:573-575, Sept. 8, 1984.

105. Melbye, M., Froebel, K.S., Madhok, R., et al., "HTLV-III Seropositivity in European Haemophiliacs Exposed to Factor VIII Concentrate Imported From the USA," *Lancet* 2:1444-1446, Dec. 22/29, 1984.

106. Montagnier, L., "Characterization of LAV—Part I," presented at the HTLV Symposium, sponsored by the National Cancer Institute, National Institutes of Health, Bethesda, MD, Dec. 6 and 7, 1984.

107. Montagnier, L., Chermann, J.C., Barre-Sinoussi, F., et al., "A New Human T-Lymphotropic Retrovirus: Characterization and Possible Role in Lymphadenopathy and Acquired Immune Deficiency Syndrome," pp. 363-379 in R.C. Gallo, M.E. Essex, and L. Gross (eds.), *Human T-Cell Leukemia/Lymphoma Viruses, The Family of Human T-Lymphotropic Retroviruses: Their Role in Malignancies and Association With AIDS* (Cold Spring Harbor, NY: Cold Spring Harbor Laboratory, 1984).

108. Montagnier, L., Gruest, J., Chamaret, S., et al., "Adaptation of Lymphadenopathy Associated Virus (LAV) to Replication in EBV-Transformed B Lymphoblastoid Cell Lines," *Science* 225:63-66, July 6, 1984.

109. Morin, S.F., "AIDS in One City: An Interview With Mervyn Silverman, Director of Health, San Francisco," *Am. Psychologist* 39:1294-1296, November 1984.

110. Morin, S.F., Charles, K. A., and Malyon, A. K., "The Psychological Impact of AIDS on Gay Men," *Am. Psychologist* 39:1288-1293, November 1984.

111. Moss, B., Smith, G.L., Gerin, J.L., et al., "Live Recombinant Vaccinia Virus Protects Chimpanzees Against Hepatitis B," *Nature* 311:67-69, Sept. 6, 1984.

112. National Coalition of Gay Sexually Transmitted Disease Services, "Guidelines and Recommendations for Healthful Gay Sexual Activity" (brochure, 3rd ed.), Milwaukee, WI, 1983.

113. National Gay Task Force and Lambda Legal Defense and Education Fund, "Confidentiality and AIDS-Related Research," briefing paper for the PHS AIDS Executive Committee, Dec. 3, 1984.

113a. New York City Department of Health, Board of Health, Resolution pertaining to the serologic test for the virus associated with AIDS, adopted Oct. 17, 1984.

114. New York State Department of Health, New York State Council on Human Blood and Transfusion Services, "Blood Donor Screening Policy Recommendations" (untitled news release), Albany, NY, July 31, 1984.

115. Nicholson, J.K.A., McDougal, J.S., Spira, T.J., et al., "Immunoregulatory Subsets of the T Helper and T Suppressor Cell Populations in Homosexual Men With Chronic Unexplained Lymphadenopathy," *J. Clin. Invest.* 73:191-201, January 1984.

116. Novick, A., "At Risk for AIDS: Confidentiality in Research and Surveillance," *IRB: A Review of Human Subjects Research* 6(6):10-11, November/December 1984.

117. Panem, S., "AIDS, Public Policy and Biomedical Research," *Chest* 85:416-422, March 1984.

118. Papaevangelou, G., Economidou, J., Kallinikos, J., et al., "Lymphadenopathy Associated Virus in AIDS, Lymphadenopathy Associated Syndrome, and Classic Kaposi Patients in Greece" (letter), *Lancet* 2:642, Sept. 5, 1984.

119. Pickelsimer, S., Financial Management Branch, Centers for Disease Control, Atlanta, GA, personal communication, Nov. 13, 1984.

120. Piot, P., Taelman, H., Minlangu, K.B., et al., "Acquired Immunodeficiency Syndrome in a Heterosexual Population in Zaire," *Lancet* 2:65-69, July 14, 1984.

121. Pitlick, F., Division of Blood Diseases and Resources, National Heart, Lung, and Blood Institute, National Institutes of Health, comments made at the NHLBI AIDS Working Group meeting, Bethesda, MD, Sept. 10, 1984.

122. Popovic, M., Sarngadharan, M.G., Read, E., et al., "Detection, Isolation, and Continuous

Production of Cytopathic Retroviruses (HTLV-III) From Patients With AIDS and Pre-AIDS," *Science* 224:497-500, May 4, 1984.

123. Primsleur, J.L., "Mayor Furious Over 'Dumping' of AIDS Victim," *San Francisco Chronicle*, p. 1, Oct. 1, 1983.
124. Purtilo, R., Sonnabend, J., and Purtilo, D.T., "Confidentiality, Informed Consent and Untoward Social Consequences in Research on a 'New Killer Disease' (AIDS)," *Clin. Research* 31(4):462-472, 1983.
125. Quinn, T.C., "Perspectives on the Future of AIDS (editorial)," *J.A.M.A.* 253:247-249, Jan. 11, 1985.
126. Raine, A.E.G., Ilgren, E.B., Kurtz, J.B., et al., "HTLV-III Infection and AIDS in a Zambian Nurse Resident in Britain" (letter), *Lancet* 2:985, Oct. 27, 1984.
127. Safai, B., Groopman, J.E., Popovic, M., et al., "Seroepidemiological Studies of Human T-Lymphotropic Retrovirus Type III in Acquired Immunodeficiency Syndrome," *Lancet* 1:1438-1440, June 30, 1984.
128. Safer Sex Committee of New York, "Healthy Sex Is Great Sex" (brochure), New York, NY, no date.
129. Salahuddin, S.Z., Groopman, J.E., Markham, P.D., et al., "HTLV-III Symptom-Free Seronegative Persons," *Lancet* 2:1418-1420, Dec. 22/29, 1984.
130. Sarngadharan, M.G., Popovic, M., Bruch, L., et al., "Antibodies Reactive With Human T-Lymphotropic Retroviruses (HTLV-III) in the Serum of Patients With AIDS," *Science* 224:506-508, May 4, 1984.
131. Saxinger, C., "The Epidemiology of HTLV in Africa," presented at the HTLV Symposium, sponsored by the National Cancer Institute, National Institutes of Health, Bethesda, MD, Dec. 6 and 7, 1984.
132. Schupbach, J., Popovic, M., Gilden, R.V., et al., "Serological Analysis of a Subgroup of Human T-Lymphotropic Retroviruses (HTLV-III) Associated With AIDS," *Science* 224:503-505, May 4, 1984.
133. Seligmann, M., Chess, L., Fahey, J.L., et al., "AIDS—An Immunologic Reevaluation," *N. Engl. J. Med.* 311:1286-1292, Nov. 15, 1984.
134. Shaw, G.M., Hahn, B.H. Arya, S.K., et al., "Molecular Characterization of Human T-Cell Leukemia (Lymphotropic) Virus Type III in the Acquired Immune Deficiency Syndrome," *Science* 226:1165-1171, Dec. 7, 1984.
135. Shaw, G.M., Harper, M.E., Hahn, B.H., et al., "HTLV-III Infection in Brains of Children and Adults With AIDS Encephalopathy," *Science* 227:177-182, Jan. 11, 1985.
136. Shepard, B., Centers for Disease Control, Atlanta, GA, personal communication, Oct. 16, 1984.
137. Smith, G.L., Mackett, M., and Moss, B., "Infectious Vaccinia Virus Recombinants That Express Hepatitis B Virus Surface Antigen," *Nature* 302:490-495, Apr. 7, 1983.
138. Snyder, M., Director, Division of Preclinical Research, National Institute on Drug Abuse, Rockville, MD, personal communication, Jan. 14, 1985.
139. Snyder, M., Stover, E., and Ginzburg, H., et al., Alcohol, Drug Abuse, and Mental Health Administration, Bethesda, MD, personal communication, Aug. 31, 1984.
140. Sodroski, J., Rosen, C., Wong-Staal, F., et al., "*Trans*-Acting Transcriptional Regulation of Human T-Cell Leukemia Virus Type III Long Terminal Repeat," *Science* 227:171-173, Jan. 11, 1985.
141. Spira, T.J., Des Jarlais, D.C., Marmor, M., et al., "Prevalence of Antibody to Lymphadenopathy-Associated Virus Among Drug-Detoxification Patients in New York" (letter), *N. Engl. J. Med.* 311:467-468, Aug. 16, 1984.
142. Talbot, B., National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD, personal communication, Nov. 5, 1984.

142a. Tenner-Racz, K., Racz, P., Dietrich, M., et al., "Altered Follicular Dendritic Cells and Virus-Like Particles in AIDS and AIDS-Related Lymphadenopathy," *Lancet* 1:105-106, Jan. 12, 1985.

143. U.S. Conference of Mayors, *Local Responses to Acquired Immune Deficiency Syndrome (AIDS): A Report of 55 Cities* (Washington, DC: U.S. Conference of Mayors, November 1984).
144. U.S. Congress, House of Representatives, "Making Supplemental Appropriations for the Fiscal Year Ending September 30, 1984, and for Other Purposes," Conference Report 98-977 (to accompany H.R. 6040), Aug. 10, 1984.
145. U.S. Congress, House Committee on Appropriations, Subcommittee on Labor, Health, and Human Services, *Hearings on Departments of Labor, HHS, Education Appropriations for 1984*, parts 3 and 4a (Washington, DC, 1983).
146. U.S. Congress, House Committee on Government Operations, *The Federal Response to AIDS*

(Washington, DC: U.S. Government Printing Office, 1983).

147. U.S. Department of Health and Human Services, Public Health Service, "What Everyone Should Know About AIDS" (brochure prepared by Channing L. Bete Co., Inc., S. Deerfield, MA), 1984.

148. U.S. Department of Health and Human Services, Public Health Service, "What Gay and Bisexual Men Should Know About AIDS" (brochure prepared by Channing L. Bete Co., Inc., S. Deerfield, MA), 1984.

149. U.S. Department of Health and Human Services, Public Health Service, "Why You Should Be Informed About AIDS" (brochure prepared by Channing L. Bete Co., Inc., S. Deerfield, MA), 1984.

150. U.S. Department of Health and Human Services, Public Health Service, "AIDS Public Health Service Total," xerox copy provided by W.H. Little, Office of the Assistant Secretary for Health, dated July 27, 1984 and Sept. 11, 1984.

151. U.S. Department of Health and Human Services, Public Health Service, Alcohol, Drug Abuse, and Mental Health Administration, "Chronology of Activities Related to AIDS in Fiscal Years 1983-84," memorandum to Office of Technology Assessment, U.S. Congress, Sept. 24, 1984.

152. U.S. Department of Health and Human Services, Public Health Service, Alcohol, Drug Abuse, and Mental Health Administration, "ADAMHA AIDS Research," xerox copy dated Dec. 14, 1984.

153. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, "Prevention of Acquired Immune Deficiency Syndrome (AIDS): Report of Interagency Recommendations," *Morbidity and Mortality Weekly Report* 32:101-103, Mar. 4, 1983.

154. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, "Antibodies to a Retrovirus Etiologically Associated With Acquired Immunodeficiency Syndrome (AIDS) in Populations With Increased Incidences of the Syndrome," *Morbidity and Mortality Weekly Report* 33:377-379, July 13, 1984.

155. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, "Experimental Infection of Chimpanzee With Lymphadenopathy-Associated Virus," *Morbidity and Mortality Weekly Report* 33:442-443, Aug. 3, 1984.

156. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, "Update: Acquired Immunodeficiency Syndrome (AIDS) in Persons With Hemophilia," *Morbidity and Mortality Weekly Report* 33:589-591, Oct. 26, 1984.

157. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, "Update: Acquired Immunodeficiency Syndrome—United States," *Morbidity and Mortality Weekly Report* 33:661-664, Nov. 30, 1984.

158. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, comments accompanying letter from E.N. Brandt, Jr., Assistant Secretary for Health, Public Health Service, U.S. Department of Health and Human Services, to Office of Technology Assessment, U.S. Congress, Dec. 20, 1984.

159. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, "Provisional Inter-Agency Recommendations for Screening Donated Blood and Plasma for Antibody to the Virus Causing Acquired Immunodeficiency Syndrome," *Morbidity and Mortality Weekly Report* 34:1-5, Jan. 11, 1985.

159a. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, "Update: Acquired Immunodeficiency Syndrome—Europe," *Morbidity and Mortality Weekly Report* 34:21-31, Jan. 18, 1985.

160. U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, comments accompanying letter from Edward N. Brandt, Jr., Assistant Secretary for Health, Public Health Service, U.S. Department of Health and Human Services, to Office of Technology Assessment, U.S. Congress, Dec. 20, 1984.

161. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Cancer Institute, "HTLV Symposium," Bethesda, MD, Dec. 6 and 7, 1984.

162. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Cancer Institute, letter to Office of Technology Assessment, U.S. Congress, Dec. 11, 1984.

163. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Cancer Institute, Division

of Cancer Etiology, Board of Scientific Counselors, Bethesda, MD, letter to The Honorable Alan Cranston, U.S. Senate, Oct. 19, 1984.

164. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Cancer Institute and Centers for Disease Control, "Summary of the Workshop on Kaposi's Sarcoma," xerox copy dated Sept. 15, 1981.
165. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Institute of Allergy and Infectious Diseases, Bethesda, MD, Interview Schedules for Five-City Study, copies provided by R. Kaslow, December 1984.
166. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Institute of Allergy and Infectious Diseases, Bethesda, MD, personal communication, December 1984.
167. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, Office of the Director, Office for Protection from Research Risks, consent form for "Blood Transfusion Safety Study," Bethesda, MD, Aug. 27, 1984.
168. U.S. Executive Office of the President, Office of Management and Budget, Budgets of the U.S. Government, 1984 and 1985.
169. U.S. Executive Office of the President, Office of Management and Budget, Circular No. A-11 (Revised): "Preparation and Submission of Budget Estimates," Transmittal Memorandum No. 55, Washington, DC, July 2, 1984.
170. Van de Perre, P., Lepage, P., Kestelyn, P., et al., "Acquired Immunodeficiency Syndrome in Rwanda," *Lancet* 2:62-65, July 14, 1984.
171. Vilmer, E., Fischer, A., Griscelli, C., et al., "Possible Transmission of a Human Lymphotropic Retrovirus (LAV) From Mother to Infant With AIDS (letter)," *Lancet* 2:229-230, July 28, 1984.
172. Vilmer, E., Rouzioux, C., Brun-Vezinet, F., et al., "Isolation of New Lymphotropic Retrovirus From Two Siblings With Haemophilia B, One With AIDS," *Lancet* 1:753-757, Apr. 7, 1984.
173. Ward, J., Epidemic Intelligence Service Officer, AIDS Activity, Centers for Disease Control, Atlanta, GA, personal communication, Dec. 18, 1984.
174. Weiss, S.H., Goedert, J.J., Sargadharan, et al., "Screening Test for HTLV-III (AIDS Agent) Antibodies: Specificity, Sensitivity, and Applications," *J.A.M.A.* 253:221-225, Jan. 11, 1985.
175. Wehling, J.R., Financial Management Branch, National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, MD, personal communications, Nov. 8, 1984; December 1984.
176. Wells, S.A., Jr., Chairman, Board of Scientific Counselors, Division of Cancer Treatment, National Cancer Institute, National Institutes of Health, Bethesda, MD, letter to J.B. Wyngaarden, Director, National Institutes of Health, Nov. 7, 1984.
177. Wilburn, C., Food and Drug Administration, Rockville, MD, personal communication, Nov. 5, 1984.
178. Wong-Staal, F., "Advances in Molecular Analysis of HTLV-I, HTLV-II, and HTLV-III," presented at the HTLV Symposium, sponsored by the National Cancer Institute, National Institutes of Health, Bethesda, MD, Dec. 6 and 7, 1984.
179. Wyngaarden, J., Director, National Institutes of Health, Bethesda, MD, personal communication, Sept. 18, 1984.
180. Yarchoan, R., "New Strategies for the Therapy of AIDS," presented at the HTLV Symposium, sponsored by the National Cancer Institute, National Institutes of Health, Bethesda, MD, Dec. 6 and 7, 1984.
181. Zagury, D., Bernard, J., Leibowitch, J., et al., "HTLV-III in Cells Cultured From Semen of Two Patients With AIDS," *Science* 226:449-451, Oct. 26, 1984.
182. Zoler, M.L., "Anti-Idiotypic Antibodies: A Safer Way To Immunize Against AIDS?" *Biotechnology* 2:926-927, November 1984.

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Office of Technology Assessment

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OTA-TM-H-24 FEBRUARY 1985